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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

H.R. 2990/H.R. 3566

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1990, AND FOR OTHER PURPOSES

Part 2 (pages 1-1257)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Printed for the use of the Committee on Appropriations

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

MONDAY, APRIL 10, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 1:26 p.m., in room SD-116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Inouye, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF LOUIS W. SULLIVAN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will come to order.

Good afternoon. I want to welcome Secretary Sullivan here this afternoon to the kickoff hearing to review the fiscal year 1990 budget proposal for the Department of Health and Human Services.

The total fiscal 1990 budget request for the Department is $121.4 billion, of which $16.8 billion is for discretionary programs and $104.6 billion is for mandatory appropriations over which this subcommittee has very little control.

In addition, the Department will spend an estimated $306 billion from the permanent trust funds in fiscal year 1990. Total annual spending in fiscal year 1990 will, therefore, be $426.8 billion, making the Department of Health and Human Services the fourth largest budget in the world, smaller only than the entire Federal budget and smaller than only the national budgets of the Soviet Union and Japan.

This afternoon's hearing will be followed by six additional hearings to permit us to review in greater detail the requests of the various agencies included within the Department of Health and Human Services.

This afternoon's hearing will permit us to review with Secretary Sullivan several matters of broad policy significance. We are particularly pleased to have Secretary Sullivan assume the important responsibility of presiding over the world's fourth largest budget.

Dr. Sullivan has had a distinguished career as a medical educator and served as the president and dean of the Medical College at Morehouse College in Atlanta. He is a person of broad talent and I look forward to a cooperative and mutually supportive relationship with the Department under Dr. Sullivan's leadership.

This afternoon I would like to discuss a number of issues. First, Dr. Sullivan, we must, all of us, commit ourselves to ending the scourge of drugs in our society. Yet, of the $805 million appropriated to the Alcohol, Drug Abuse, and Mental Health Administration for this purpose for fiscal year 1989, less than $200 million has gone to the States and 16 States have not yet received any funds. So hopefully, Dr. Sullivan, you can break this logjam and get the drug treatment and prevention money out where it can be of use.

Second, we have now provided $45 million since 1988 to pay for AZT for AIDS patients who cannot afford this life-protecting drug. However, it has not been agreed that AZT funding is to become an entitlement. The appropriations for AZT are one-time stopgap measures.

Hopefully, Dr. Sullivan, we will in the very near future develop a policy to address this very important funding issue.

Third, there is a great deal of misinformation and confusion about catastrophic health care in Iowa and across the country. Hopefully, Secretary Sullivan can launch further educational efforts focused on our Medicare-eligible citizens.

Finally, Secretary Sullivan, there is a rural health and safety crisis in this country. Rural hospitals are closing. It is getting more and more difficult to acquire proper and timely medical care in many rural areas. Hopefully, Secretary Sullivan can be attentive to these needs and we can see a shift toward improved health care availability for those in rural areas. And after your testimony I will have a number of questions about that, Dr. Sullivan.

So these are a few of the issues that I hope to discuss with Secretary Sullivan this afternoon. But over all of this, Mr. Secretary, is the impact that we will have this year on the deficit. We all need to find ways to reduce Government costs without causing any serious damage to the very necessary services that the Government provides.

We need to find additional efficiencies; we need to eliminate duplication and overlap. We need to eliminate fraud and wasteful spending.

I want you to know I will work closely with you and the Department in this area so that we can meet the necessary needs that this Department has to provide, but to find those areas where we can streamline, become more efficient, cut waste, cut fraud, cut duplication, so that we can make our dollars go further.

So, I say that sort of overrides everything that we are doing this year.

At this point, I would leave the record open for any opening statement that Senators may wish to make, and Senator Cochran will have an opening statement for the record at this point.

[The statement follows:]

STATEMENT OF SENATOR THAD COCHRAN

Mr. Chairman, I join you and the other members of the Subcommittee in welcoming Dr. Louis Sullivan, our new Secretary of Health and Human Services, in his first appearance before us.

Dr. Sullivan, I look forward to working with you as we address the many challenges facing our Nation in the areas under the jurisdiction of your Department.

I am sure that you will be able to use your experience and expertise in the field of medicine as a valuable resource as you administer the health programs of the Department.

In Mississippi, we are faced with the possibility of having to close or modify the mission of some small rural hospitals. There are problems, too, of increasing health care costs and high infant mortality rates. In addition, we have a large elderly population, who are troubled about long term health care and its availability and cost.

As a member of not only this subcommittee, but also the authorizing committee, I expect that we will be addressing these issues in the months to come. I am confident that you can be one of the best leaders we have ever had as Secretary of this important Department in helping find and develop solutions to meet the health care needs of all Americans.

Thank you again for your cooperation with this subcommittee.

PREPARED STATEMENT

Senator HARKIN. Dr. Sullivan, your entire statement will be made a part of the record. At this time, again, you are welcome to the subcommittee. If you would please summarize your statement for us.

[The statement follows:]

STATEMENT OF LOUIS W. SULLIVAN

Mr. Chairman, Members of the Committee, I am pleased to be here today in my first appearance before this Subcommittee since my confirmation by the Senate. I wish to discuss with you President Bush's budget proposals for health and human services. I am pleased to enjoy the trust of our new President, and as Secretary of Health and Human Services, I shall carry out the task he has given me in such a way that the hopes and aspirations we mutually hold for this Department, and for the American people, are fulfilled.

Today, I am privileged to have the opportunity to discuss with this distinguished Subcommittee the broad contours of those hopes and aspirations. They center on the President's commitment -- a commitment I fully share -- to the ideal of a "kinder, gentler" America. No Department will be more directly affected by that commitment than HHS, which touches the lives of Americans wherever they are most vulnerable -- from the beginning of life, through health and sickness, from the foods we eat to the medicines we take, to the care of our elderly and disabled among us.

Taking that commitment as my guide, I intend to see to it that our policies at HHS carry a firm, but gentle touch; that HHS employees take pride in the invaluable service they render our citizens; that government itself comes to have a more human face. Bringing a new spirit of kindness and compassion to a vast federal Department may seem excessively idealistic. But it is an ideal we can and must attain. Nothing less shall be my goal as Secretary of HHS.

During my medical career, I have seen remarkable progress in our nation's system of health care, with programs like Medicare and Medicaid making health care more available to the elderly and to

the poor. And I have seen the improvements in the lives of millions of our children and less privileged through HHS' programs of human services.

Let me indicate how we might begin to make further progress toward improving the health and well-being of our citizens.

First, we must assure the solvency of programs like Social Security and Medicare. We must find ways to contain escalating medical costs, without sacrificing our commitment to quality health care for all. And we must emphasize health promotion and preventive medicine strategies, because promoting health is ultimately more humane and economical than merely treating illness.

Second, we must sustain and improve programs like Head Start and Aid to Families with Dependent Children -- programs that help the poor learn and work their way out of poverty. Implementation of last year's Family Support Act will therefore be one of my highest and earliest priorities.

The Act's most fundamental change was the creation of a new program of work and training activities, the Job Opportunities and Basic Skills (JOBS) training program, which all states must have in effect by October, 1990. States can elect to replace existing work programs with JOBS as early as July of this year. I intend to insure a speedy implementation of this Act, with the issuance of program regulations early this Spring. We must do all that we can to encourage welfare recipients to become productive members of this country's workforce.

Welfare reform also made improvements to child support enforcement, and I want to report to the Committee that child support collections continue to rise. We project that increases in 1990 will exceed 1989 estimates by 17 percent, or

$931 million. The strong Congressional commitment to enforcement activities has helped bring this important parental financial responsibility issue to the forefront in State capitals across the country.

Preschool children from low-income families must be encouraged and given the opportunity to develop all of their talents. Head Start has been doing this for over 20 years and President Bush's budgetary priorities include $1.5 billion for this program -- a 20 percent expansion. This $250 million increase will allow up to 95,000 additional four-year olds, nearly 550,000 children in total, to be enrolled in Head Start centers across the country developing skills and enriching their minds and bodies.

Third, we must seek ways to strengthen family life and reinforce our society's sense of community, our shared sense of responsibility and commitment to one another. As President Bush notes, "family . . . is a powerful word, full of emotional resonance," and those of us who have been blessed with strong families must work to bring that blessing to those who have not. Attention to family means that the health of our children must be our particular concern, for nothing less than our nation's future is at stake. Today, that future is threatened by the epidemic of drug abuse among our young. I am deeply committed to the battle against this scourge, and will work long and hard with this Committee, with the President, and with his Drug Advisor in pursuit of victory.

Young people must be educated to recognize the destructive impact of illegal drug use. President Bush has requested $35 million to initiate a new program to stimulate community partnerships -- parents, schools, businesses, and community leaders -- in order to develop innovative drug abuse prevention strategies. We also must do more to help drug abusers reclaim healthy lives. The budget priorities of President Bush include $30 million for a

new treatment initiative to aid communities with severe drug problems to expand treatment services, especially for the indigent, disadvantaged, youth and expectant mothers.

These initiatives of President Bush to reduce drug abuse are built on the substantial array of programs started through the Anti-Drug Abuse Acts of 1986 and 1988. The Alcohol, Drug Abuse and Mental Health Administration will be spending an additional $700 million on a variety of prevention and research approaches, as well as assisting communities in the expansion of treatment services and combatting the problem of IV drug use and AIDS transmission.

We must also remove barriers to adoption, to help ensure that all children have an opportunity to grow up in a loving family and a safe and nurturing home environment. The budget priorities of President Bush include fully funding adoption assistance payments to families adopting special needs children, complemented by a Federal income tax deduction for one-time costs of adoption.

Caring for the needs of the homeless exemplifies our commitment to one another. By fully funding the McKinney Act, this Department will assist communities in bringing to the homeless critical primary health care services, mental health care, and a wide assortment of social services. A total of $189 million is directed to these specialized McKinney Act programs. In addition, the Department will be targeting the homeless through other programs -- runaway youth, community support for chronically mentally ill, and Medicaid non-traditional clinical services.

Fourth, we must sustain our biomedical research efforts in the quest for a cure for AIDS. As the President has said, "We must commit the resources and the will to find a cure. American science must know that we have the resolve to beat this disease."

At the same time, however, we must not slight our efforts to conquer cancer, heart disease, diabetes, arthritis, and other disorders afflicting our citizens.

The Public Health Service will be spending $1.6 billion in 1990, a 24 percent increase, on a wide array of AIDS research, prevention, and education activities. This unprecedented and enormous Federal fight against AIDS, was advanced so rapidly only because of the knowledge gained through biomedical research over the last half-century.

In 1990, additional AIDS funds are requested for all aspects of the PHS program of research and prevention. These efforts will be guided by the recommendations of the Presidential Commission on the Human Immunodeficiency Virus Epidemic and the 1988 Public Health Service Charlottesville AIDS Planning Conference Report. Emphasis will be placed on expanding support for developing and applying various therapeutic intervention strategies, including targeting intravenous drug abusers; and on increasing efforts to provide accurate and up-to-date information to high-risk groups, minority populations, adolescents, health care providers, and the general public on how to reduce the chances of becoming infected with HIV.

The National Institutes of Health, the embodiment of biomedical research in this country and recognized worldwide for its excellence, will have $6.8 billion available in 1990 for research on a variety of diseases, in addition to the $753 million targeted for AIDS. The budget for NIH continues to place emphasis on the support of basic research. Through the conduct, support and promotion of basic biomedical research, new information is gained about the processes underlying human health. The human genome project, budgeted at $100 million, is a prime example of how enhanced information, through the mapping of the human genome, will result in significant benefits to mankind.

Proceeding with this type of scientific work depends on long-term commitments. The Federal government has a financial responsibility for basic research to fulfill its obligation for today and recognize the promise of the future.

Finally, we must focus our limited resources on the poor, the disadvantaged, and the neglected in our society. At the same time, we must focus first on the populations most at risk -- mothers and children. Programs like Medicaid must be carefully administered so that rural and inner city health care needs are met, and the nation's poor are accorded decent care with dignity. We will soon send to the Congress legislation to enhance Medicaid services for children, including expansion of immunization services.

We are requesting full funding for Medicaid benefits; Supplemental Security Income benefits to the aged, disabled, and the blind; and for AFDC benefit payments.

In summary, I would like to reiterate what the President and other Administration members have already stated. We are prepared to work together with the Congress in a bi-partisan spirit, and to put forth whatever level of effort it takes to reach a constructive budget agreement.

In that spirit, I would be pleased to try to respond to your questions, and I thank you again for inviting me to appear before you today.

OVERVIEW

Secretary SULLIVAN. Thank you very much, Mr. Chairman. I am very grateful for this opportunity to appear before your committee. Indeed, this is my first appearance before this subcommittee since my confirmation on March 1.

I am pleased to enjoy the trust of President Bush, as his Secretary of Health and Human Services, and as such I shall carry out the tasks he has given me in such a way that the hopes and aspirations that we mutually hold for this Department and for the American people are fulfilled.

I am privileged to have the opportunity to discuss with this distinguished committee the broad contours of those hopes and aspirations. They center on the President's commitment, which I fully share, to the ideal of a kinder and gentler America.

My Department is directly involved in that commitment of our President, which touches on the lives of all of our citizens when they are most vulnerable—from the beginning of life, through health and sickness, from our foods, our medicines, and to the elderly and disabled among us.

In my leadership of this Department, I intend to see that our policies carry a firm but gentle touch, and further that our employees take pride in the service that they render to our citizens to see that our Department comes to have a more human face and our regulations are firm, though gentle.

During my career I have seen remarkable progress in our Nation's system of health care, with programs such as Medicare and Medicaid making care available to the elderly and to the poor, services available prior to this time only to the wealthy.

Let me outline in a broad way some of our priorities. First, we must ensure the solvency of programs like Social Security and Medicare. We also must find ways, as you have indicated, to contain our escalating medical costs without sacrificing our commitment to quality.

We must emphasize health promotion and preventive medicine strategies, because promoting health is ultimately more humane and economical than merely preventing illness.

Second, we must sustain and improve programs like Head Start and aid to families with dependent children, programs that help our poor learn and help them work their way out of poverty. Thus, implementation of last year's Family Support Act will be one of my highest and earliest priorities.

The act's most fundamental change was the creation of a new program of work and training activities, the Jobs Opportunities and Basic Skills [JOBS] Training Program, which all States must have in effect by October 1990. States can elect to replace existing work programs with JOBS as early as July of this year.

I intend to assure speedy implementation of this act, with the issuance of program regulations early this spring. We must do all that we can to encourage welfare recipients to become productive members of our country's work force.

Welfare reform also made improvements to child support enforcement, and I wanted to report to this subcommittee that child support collections continue to rise. We project that increases in

1990 will exceed 1989 estimates by 17 percent or a total of $931 million. The strong congressional commitment to enforcement activities has helped bring this important parental financial responsibility issue to the forefront in State capitals across the country.

Preschool children from low-income families must be encouraged and given the opportunity to develop all of their talents. Head Start has been doing this for over 20 years, and President Bush's budgetary priorities include $1.5 billion for this program, a 20-percent expansion. This increase of $250 million for this program will allow up to 95,000 additional 4 year olds, or nearly 550,000 children in all, to be enrolled in Head Start centers across the country, developing skills and enriching their minds and bodies.

Third, we must seek ways to strengthen family life and reinforce our society's sense of community, our shared sense of responsibility and commitment to one another. As our President has noted, family is a powerful word, full of emotional resonance, and those of us who have been blessed with strong families must work to bring that blessing to those who have not.

This means that the health of our children must be our particular concern, for indeed our Nation's future is at stake. As you have noted, today that future is threatened by the epidemic of drug abuse among our young. I am deeply committed to the battle against this scourge and will work long and hard with this subcommittee, our President, and his drug advisor in pursuit of victory.

Our young people must be educated to recognize the destructive impact of illegal drug use. President Bush has thus requested $35 million to initiate a new program to stimulate community partnerships—involving parents, schools, businesses, and community leaders—in order to develop innovative drug abuse prevention strategies. We must also do more to help drug abusers reclaim healthy lives.

BUDGET PRIORITIES

The budget priorities include $30 million for a new treatment initiative to aid communities with severe drug problems to expand treatment services, especially for the indigent, for the disadvantaged, and for our young people and expectant mothers.

These initiatives to reduce drug abuse are built on the substantial array of programs started through the Anti-Drug Abuse Acts of 1986 and 1988. ADAMHA will be spending an additional $700 million on a variety of prevention and research approaches, as well as assisting communities in the expansion of treatment services and combating the problem of IV drug abuse and AIDS transmission.

We must also reduce barriers to adoption, to help ensure that all children have an opportunity to grow up in a loving family and a safe and nurturing home environment. The budget priorities of President Bush include fully funding adoption assistance payments to families adopting special needs children, complemented by a Federal income tax deduction for one-time costs of adoption.

Caring for the needs of the homeless exemplifies our commitment to one another. By fully funding the McKinney Act, this Department will assist communities in bringing to the homeless critical primary health care services, mental health care, and a wide

variety of social services. We have already had one meeting of our joint homeless task force chaired by Secretary Kemp.

A total of $189 million is directed to these specialized McKinney Act programs. In addition, the Department will be targeting the homeless through other programs, including runaway youth, community support for chronically mentally ill, and Medicaid nontraditional clinical services.

Fourth, we must sustain our biomedical research efforts in the quest for a cure for AIDS. As the President has said: "We must commit the resources and the will to find a cure. American science must know that we have the resolve to beat this disease."

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AIDS REQUEST

In 1990, additional AIDS funds are requested for all aspects of the Public Health Service program of research and prevention. These efforts will be guided by the recommendations of the Presidential Commission on the HIV Epidemic and the 1988 Public Health Service Charlottesville AIDS Planning Conference report.

Emphasis will be placed on expanding support for developing and applying various therapeutic intervention strategies, including targeting intravenous drug abusers, and on increasing efforts to provide accurate and up-to-date information to high-risk groups, including minority populations, adolescents, health care providers, and the general public on how to reduce the chances of becoming infected with this virus.

The National Institutes of Health, which are the embodiment of biomedical research in this country and recognized worldwide for its excellence, will have $6.8 billion available in 1990 for research on a variety of diseases, in addition to the $753 million targeted for AIDS research.

BIOMEDICAL RESEARCH

The budget for NIH continues to place emphasis on the support of basic research. Through the conduct, support, and promotion of basic biomedical research, new information is gained about the processes underlying human health.

The human genome project, budgeted at $100 million, is a prime example of how enhanced information through the mapping of the human genome will result in significant benefits to mankind.

Proceeding with this type of scientific work depends on long-term commitments. The Federal Government has a financial responsibility for basic research to fulfil its obligations for today and recognize the promise of the future.

Finally, in an era of limited resources we must focus those resources on the poor, on the disadvantaged, and the neglected in our society. At the same time, we must focus first on the populations most at risk, mothers and children. Programs like Medicaid must be carefully administered so that rural and inner city health care needs are met and that the Nation's poor are accorded decent care with dignity.

MEDICAID ENHANCEMENTS

We will soon send to the Congress legislation to enhance Medicaid services to children, including expansion of immunization services. We are requesting full funding for Medicaid benefits, supplemental income benefits to the aged, disabled, and the blind, and for AFDC benefit payments.

In summary, I would like to repeat what President Bush and other members of his administration have already stated: We are prepared to work together with the Congress in a bipartisan spirit and to put forth whatever level of effort it takes to reach a constructive budget agreement.

In that spirit, I am pleased to try to respond to your questions, and again I am pleased to appear before you today.

Senator HARKIN. Mr. Secretary, thank you very much.

Before I get to my regular questions here, on your last page you said that you will soon send to the Congress legislation to enhance the Medicaid services for children, including expansion of immunization services.

Secretary SULLIVAN. Yes, sir.

Senator HARKIN. Are you going to have a recommended amount of money for that and where we are going to get it?

Secretary SULLIVAN. That will be part of the discussion between the administration and the Congress. We are committed to funding the Medicaid program enhancements.

Senator HARKIN. Do you know how much? Do you have any idea how much you are going to request in terms of money for that?

Secretary SULLIVAN. These proposed initiatives are expected to cost $85 million.

Senator HARKIN. Enhanced—and this is almost all for immunization?

Secretary SULLIVAN. We estimate $5 million for the cost of the additional immunization coverage and the remaining $80 million will be spent on program expansions for infants and pregnant women.

Senator HARKIN. Well, I hope you also send along some requests where we are going to get the money, too. I would like to have a little help on that.

Mr. Secretary, let me first turn to the overall area that I talked about, about the necessity to reduce the deficit. We all agree on it. The administration agrees on it, we agree on it in Congress. We have to reduce the deficit.

But then again, of all the departments, your Department is the one charged with the responsibility of making sure that those most vulnerable in our society are not the ones on whose backs we bal-

ance the budget. Yours is the Department that indeed can carry out the Bush promise of a kinder and gentler America.

So while I put a lot of emphasis on reducing spending, I am convinced that there are areas in this budget in which we can make cuts, in which we can tighten down on things that will free up money for things like immunization for more kids.

MEDICARE CONTRACTORS

We had a number of examples. I covered one earlier dealing with Medicare contractors. Mr. Secretary, OMB cut your Department's request for Medicare contractors by nearly $400 million, which resulted in a 50-percent cut in payment safeguard activities.

I held a special oversight hearing on this issue recently, which revealed that this cut will cost the Federal Government nearly $2 billion in lost revenues, and both GAO and the inspector general's office said this was hard money, this is not blue sky type of stuff. This is hard money.

They know that if they do not have the audit activities we will not recover that $2 billion in lost revenues. If we do not have that and if the revenues are lost, it puts a greater pressure on Medicare premium increases. So GAO said that this would be penny wise and pound foolish.

Not only would it cost the taxpayers more dollars, but the elderly then will have to pay higher premiums in the future because it will cost more.

Are you aware, Mr. Secretary, that this cut of $400 million from safeguard activities would force layoffs of 2,000 personnel, including about 1,100 auditors nationwide? I wonder again if you are aware of that and what do you propose to do in your budget request to ensure that we do not lose all that money?

You see again, if you are saying to me we want to save money and cut down, here is one area right here. GAO has testified to it and the inspector general's office of HHS has testified to it. With contractor auditors, we can save $2 billion, without them we are going to lose them.

I am asking for your comments on this area.

Secretary SULLIVAN. Thank you, Senator Harkin. I would like to review this issue with my colleagues in the Department and then respond for the record. We are committed to promoting efficiency in our operations.

Senator HARKIN. I appreciate that.

[The information follows:]

The Department is aware that the proposed reduction in funding for payment safeguards will lead to layoffs of contractor personnel. To attenuate the effect of the reduction, we have asked the Office of Management and Budget to release $9.5 million from the Medicare contractors fiscal year 1989 contingency fund to finance increased Medicare Secondary Payer (MSP) activities. Two million dollars would fund research of claims from 1983 to the present for MSP noncompliance, while $7.5 million would be to match the contractors' private insurance records with the Medicare beneficiary data through negotiating modifications to current contracts.

COMPETITIVE BID PROCESS

Senator HARKIN. Another example of savings is discussed in an inspector general's report. In this case, the same company supplied

identical oxygen concentrators to the Veterans Administration and Medicare within the same geographic area. Under the Veterans Administration competitive bid process, the supplier was paid $78 per month rental, while on the Medicare side, where it was not competitively bid, they paid $300 per month rental.

Same outfit, same regulators. To quote the inspector general's report: "Medicare's payments for the rental of oxygen equipment were typically two to four times the amount paid by the VA hospitals using competitive bid contract procedures."

The report went on to state: "Almost all VA hospitals using competitive bid contracts for oxygen services were complimentary of the quality of products and degree of maintenance and other services rendered by their contractors."

Mr. Secretary, if you applied your 5 percent cut proposed to this area Medicare would still pay $285 compared to VA's $78. Do you not think these results merit your trying competitive bidding, which the inspector general says could save $200 million annually?

Secretary SULLIVAN. That is an excellent point. I will review this very carefully.

Senator HARKIN. Well, I am getting more and more into competitive bidding. Another hat I wear is chairman of the Nutrition Subcommittee. A few years ago, I found out that we were purchasing infant formula for the WIC Program under sole source contracts.

I found out we were paying upward of $1.65 for a can of formula. When we went out to competitively bid for it, we got it down to 80 cents a can, less than one-half. It is amazing. Now we can serve more people without using taxpayers' dollars.

So I would hope that you would look at this, because just using competitive bid procedures, we can save a heck of a lot of money and we can pay for this immunization program you are going to send down to us.

Secretary SULLIVAN. I will review that. The report is from our inspector general; from that perspective, we are monitoring what we are doing.

Senator HARKIN. We have him up next as soon as we are through.

Secretary SULLIVAN. Right.

Senator HARKIN. I guess what I just want to say is, I want to work with you and your Department in this area. I think one area where we can agree on a bipartisan basis and on an executive level-legislative level is in this area of getting the most bang for the buck.

What I would ask you is, if you would instruct your Department and those below you to recommend areas to us if there is anything we can do on this basis or define those areas where we can streamline, make more efficient, cut waste, cut duplication, that kind of thing. It is something that we just have to do.

I guess the Inspector General's Office is looking at it, but I would hope that your Department also would take that as one of its primary responsibilities.

Secretary SULLIVAN. We certainly will.

Senator HARKIN. And whatever we can do to help, we will.

Let me shift a little bit to the drug crisis, which as you and I pointed out, we have just got to get a handle on it. President Bush

says he is committed to ending the scourge of drugs, and you mentioned this in your testimony, Mr. Secretary.

DRUG FUNDS TO STATES

Major funding for the fight against drugs comes from the Alcohol, Drug Abuse, and Mental Health Services block grant. This committee provided over $805 million for this block grant in fiscal year 1989. We are 6 months into the year already.

Yet, I understand that less than $200 million has gone out to the States and that 16 States and the District of Columbia have not even gotten any fiscal year 1989 funds. So again my question to you is, What is the problem and how is your Department working with the States to get these funds moving?

Secretary SULLIVAN. Yes; Chairman Harkin, I have been advised by my colleagues that in almost all instances these States have not applied for the funds. The rules specify that the States must apply to HHS prior to release of those funds. We will work with the States to see that the applications are forthcoming.

Senator HARKIN. I guess that would be my followup question. If you have that many States that have not even applied, have you gone out in a proactive manner and said what is the problem? There is money committed for doing this?

Has your Department done that yet, do you know?

Secretary SULLIVAN. Not to my knowledge, but I will be reviewing that.

Senator HARKIN. I would appreciate that, too, because we are 6 months into the fiscal year. We provided the money. And again, I understand the Department is sitting on over 70 percent of the 1988 funds for the alcohol, drug treatment, and rehabilitation block grant, and even some of the 1987 funds. So we have some 1987, 70 percent of the 1988, and about 80 percent of the 1989 money.

So again I am wondering, what is going on here? Now, if there is something wrong with the procedure for the States, we need to know about this, because again this committee is charged with the responsibility of providing the money. We provide the money in a good faith manner and yet it is being blocked up someplace.

I do not know where it is and I do not know why it is, but I would ask you to find out.

Secretary SULLIVAN. I would be happy to look into this and respond for the record.

[The information follows:]

DRUG BLOCK GRANTS TO STATES

On November 18, 1988, the block grant was reauthorized and additional funds appropriated in the Anti-Drug Abuse Act of 1988 (Public Law 100-690).

On November 23, 1988, notices of funds availability and application instructions were sent to States.

As of January 1, 1989, 5 States had applied for their block grant allotments.

As of February 2, 1989, 21 States and Puerto Rico had applied for their allotments of which 12 States had received awards.

As of April 13, 1989, 35 States have been awarded 75 percent of their total fiscal year 1989 allotments, 8 States and Puerto Rico have applied for their block grant allotments, 7 States and the District of Columbia have not yet applied for their allotments.

In accordance with apportionment policies of the Office of Management and Budget, the final 25 percent will be awarded to each of the States on July 3, 1989.

BLOCK GRANT ALLOTMENTS

Senator HARKIN. Thank you. The drug bill requires the States to obligate all the funds by the end of the fiscal year, by this September. So not only should you perhaps find out why they are not, we need some suggestions from you as to how to do this.

I guess the reason I am so interested in this, is that it seems that under Mr. Bennett, the other moneys that we put out were addressing the supply side of the equation of drugs—interdiction, discovery, criminal act sanctions, that kind of thing, and the recent announcement on the District of Columbia building a new prison. We have got to do all that.

But the demand side has got to be hit just as hard. We have got to start cutting down on the demand side. That is this money, and I do not think you can do one without the other. You cannot just have a cutoff in the supply. It will find its way in someplace. We have got to cut down on the demand side also.

So I am anxious to see how these moneys go out for not only treatment, but for rehabilitation.

Secretary SULLIVAN. In addition to my commitment to review the status of those funds, we have a strong commitment to address this problem.

I have met with Dr. Fred Godwin, Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, on three occasions in the last 5 weeks, in addition to visiting his facility in Parklawn. He has briefed me on some of the research supported by ADAMHA funds, which indicated promising leads for demand reduction activities; working first with animals and second with some addicts.

We are very interested in doing everything that we can, and we will find out what the problems are with the funds going to the States.

Senator HARKIN. So, we have level funding for next year of $805 million. It was $805 million last year, too. The authorization is $1.5 billion, so we are appropriating at about 50 percent of the level of the authorization.

So it would be pretty darn tough, if, in fact, we want to hit the demand side, if States are not even applying for it, if there is some logjam someplace. We will work with you, but I want to find out why the funds are not going out.

Secretary SULLIVAN. Thank you.

Senator HARKIN. There is another area that I am somewhat concerned with. Another requirement of the 1988 act is that States must spend 50 percent of their drug abuse funds on intravenous [IV] drug abuse. Well, Iowa and some other States that do not have as much of a problem with IV drug abuse are entitled to apply for a waiver of that requirement.

Do you know if your Department has a mechanism yet for granting waivers? Do you have a mechanism to know whether or not and how we grant waivers? Again, if you do not, if you could get that to us I would appreciate it.

Secretary SULLIVAN. Yes; I will be pleased to get a response to you.

[The information follows:]

STATUS OF GUIDELINES FOR ADAMHA BLOCK GRANT IV DRUG ABUSE WAIVER

The Secretary has delegated to the Administrator of ADAMHA the authority to review and grant a State's request for a waiver of the 50 percent set-aside for IV drug abuse (section 2023 of the Anti-Drug Abuse Act of 1988, Public Law 100-690).

The guidelines for application for a waiver were prepared by the Office of Communications and External Affairs, ADAMHA, 443-3820.

The guidelines were approved by the Public Health Service on April 13, 1989, and forwarded to the Office of Management and Budget (OMB).

OMB has a minimum of 2 weeks to review the guidelines.

Upon approval of the guidelines, ADAMHA will notify each State by mail of the waiver process.

A decision on each request for waiver will be made no later than 120 days after the request is received.

CATASTROPHIC HEALTH INSURANCE

Senator HARKIN. On catastrophic health insurance, your budget request for HCFA includes $306 million for implementation of the catastrophic health insurance legislation, and that comes under our subcommittee's jurisdiction.

Do you feel these amounts are adequate to carry it out, to carry out the catastrophic health law requirements? Is $306 million adequate?

Secretary SULLIVAN. We believe so. This is the first year of implementation.

Senator HARKIN. Well, the reason I asked is that I am getting a lot of complaints in my office. I think it is the No. 1 source of mail that I now get from Iowa. Elderly people are writing in because they are confused, sometimes misinformed, and upset certainly, about the increase in their part B payments.

There seems to be—no, I am going to rephrase that. There is a definite need for some education out there, or at least for information to go out.

Now, a New York Times editorial, a few days ago, said a lot of elderly people are misinformed about the costs and benefits of catastrophic health care. I daresay this group out of California—I cannot remember the formal name of it, but they are sending out more information, more mail, than the Department is.

Quite frankly, I think a lot of what they are sending out is misinformation and I think it is designed to whip up emotions. I would even go as far as to say that I think there is a little bit of a design in there to have people send in a certain amount of money to them to continue their fight on behalf of the elderly.

Well again, I am just wondering, do you know, does your Department have any plans to educate the public about the new catastrophic health legislation?

Secretary SULLIVAN. Yes, Mr. Chairman; we have several initiatives underway. HCFA offices have an 800 phone number for individual inquiries. I think we may need to review whether that number has been adequately publicized. But I have been informed by my colleagues in the Department that that number has been very busy since the first of the year supplying information to callers.

We have been evaluating also the quality of the information that has been given. Our evaluation shows that HCFA has done well. We will be pleased to look further at the strategies of the Depart-

ment in getting information to the population, because we agree that there is a lot of misinformation and perhaps lack of information. We want to do everything to get the correct information to people.

MEDICARE RECOVERIES FROM PRIVATE INSURERS

Senator HARKIN. One other area that I wanted to cover. You may have seen the article in yesterday's Washington Post, "U.S. Seeks To Recover Billions to Medicare."

Secretary SULLIVAN. Yes.

Senator HARKIN. And then last week in the April 7 Wall Street Journal, "Has Medicare Paid Out Billions Actually Owed by Private Insurers?"

I raised this issue at a special Appropriations Committee oversight hearing that we had on February 28 this year. Again, what is your Department doing to aggressively pursue recoveries from insurance companies that owe Medicare money?

And let me just ask you a further question: Why do we not at least require the Medicare contractors who are also insurance companies to pay when they are the primary insurance?

Secretary SULLIVAN. That is the way it is supposed to operate, Mr. Chairman. The office of our inspector general, HCFA Administrator's office, and the Justice Department have been working hard to identify abuses of the program by various carriers. We have been actively uncovering these issues and referring them to the appropriate authorities, as well as negotiating with the carriers for payment. The inspector general might want to comment, too, on some of the activities that we have under way.

Senator HARKIN. I am just wondering if you think we need additional legislation in this area or not?

Secretary SULLIVAN. At this juncture, we are not prepared to recommend additional legislation. Over the past several months, staff in the inspector general's office, as well as in HCFA, have been much more active and effective than the news reports would lead you to believe.

We will be happy to get a detailed account of these activities, which have been extensive.

[The information follows:]

MEDICARE RECOVERIES

Between fiscal year 1985 and fiscal year 1988, the Health Care Financing Administration documented $5.22 billion in savings to the Medicare Trust Funds from its administration of the Medicare Secondary Payer (MSP) program. These recoveries resulted from the implementation of several administrative initiatives designed to identify MSP situations and to direct claims to the proper primary payer. These initiatives include routine beneficiary first claim development, information exchanges between Medicare contractors on MSP situations, and a special education program aimed at beneficiaries, providers, insurers and employers.

In most instances, the company repays Medicare. When the responsible insurance company does not offer an acceptable explanation for its refusal to pay, the Medicare contractor refers to case to HCFA for resolution of the matter and recovery of the payments. When HCFA has exhausted all the administrative remedies at its disposal without resolving the dispute, it refers the case to the HHS Inspector General or to the Department of Justice. HCFA has been working closely with the Department of Justice and the Inspector General's office to develop these cases and suit

has already been filed against two insurers to recover Medicare payments for services.

In the absence of a law mandating government access to the private insurance records of insurance companies, HCFA has been unable to require Medicare contractors to check their own records for MSP situations. Therefore, verification of internal records has historically been a negotiable item that contractors have repeatedly rejected in contract talks with HCFA. However, HCFA is currently preparing a legislative proposal for fiscal year 1991 that would increase its authority to mandate government access to private insurance information and thus ensure the matching of contractors' records with Medicare beneficiary data.

MEDICAL CARE COSTS

Senator HARKIN. I will break my questioning here now, respecting our time commitments, to recognize my distinguished colleague from Pennsylvania, Senator Specter.

Senator SPECTER. Well, thank you very much, Mr. Chairman.

I am delighted to see you here today, Dr. Sullivan.

Secretary SULLIVAN. Thank you.

Senator SPECTER. I am delighted to see a man of your caliber taking on a job of this magnitude. It is a gigantic undertaking. You and I have had an opportunity to work together in the past and I very much look forward to working with you in your position of Secretary of Health and Human Services.

The cost of medical care in this country is enormous. We all have to work together to find some way to provide the delivery of health care which is so necessary. I think the current statistics are $540 billion and 11.4 percent of the gross national product.

And yet, millions of Americans do not receive adequate health care, and the health issue has so many ramifications for the homeless and for people who are alcohol-dependent and drug-dependent that it is one which requires just an enormous effort.

DRUG PROGRAMS EVALUATION

But we do not have time to be discouraged, so we will plunge ahead and try to solve the problems at hand. One matter that I would like to try to talk to you initially about is the problem of drugs and rehabilitation and education to some extent, because I think that will fall under your Department as well as under the Department of Education.

The Congress authorized $1.8 billion for the drug issue in 1986 and about $770 million was allocated for education, rehabilitation, and some local support for jails and prisons. I have worked with Governor Casey in Pennsylvania and his department in trying to trace through these funds. And frankly, it has been a very slow and laborious process to see these funds come out of the various governmental departments which have responsibility for them.

One of the items that I have tried to find out about is the measuring of success of drug rehabilitation centers. And last year when your predecessor was here at our subcommittee hearings, I raised this issue with him and asked if he would provide for the record what the Department of Health and Human Services knew about evaluating the success of drug rehabilitation.

And very little was provided, and I suspect that that is more due to the difficulty of obtaining accurate information on what reha-

bilitation services are satisfactory, as opposed to any failure of the Department.

But I would like to renew that request to you today for the record, to search the records of HHS to see if your Department knows what drug rehabilitation programs have been successful.

When we drafted the 1988 legislation, we put in requirements that such statistics be maintained, but it may be that if a real effort is maintained to find out from current knowledge we could find something out. I believe that the Congress would be willing to appropriate substantial sums of money to programs which worked. But it is a matter of finding out what does work.

So that would be my initial request to you.

Along the same line, I would be interested in your thinking, to the extent you have been able to develop it so far, about what can be done on rehabilitation of drug addicts within the context of the legislation which we passed last year?

Secretary SULLIVAN. Thank you, Senator Specter. Let me thank you for your kind remarks, and look forward to working with you and your colleagues here on the subcommittee and in the Congress.

On the question of evaluation, we are in the process of awarding a contract for evaluation of drug programs. Thirty centers will be evaluated on effectiveness of their educational programs.

Senator SPECTER. How are you picking out which centers, Dr. Sullivan?

Secretary SULLIVAN. I will have to review this and get that information for you. However, those 30 community centers serve a population of approximately 20,000 people.

Senator SPECTER. I would hope that you would include Gaudenzia House in Pennsylvania, which is a unit, an institution, which has many facilities in Pennsylvania and elsewhere. That is a group that I helped found back in 1968. They are an offshoot of Daytop Village/Swan Lake, a big drug rehabilitation program in New York City.

And I have talked to them about their own success rate, and they simply do not have the resources to evaluate what it is they are doing. They are too busy trying to stop the hemorrhaging to take time to take the blood pressure. They are just too busy on the problem.

But I make that request to you. Sorry to interrupt.

Secretary SULLIVAN. We will be happy to review that. We also have a second evaluation contract that will evaluate the effectiveness of methadone treatment programs. Methadone treatment programs have been operating for 15 to 20 years here in this country.

We will review this and provide our response for the record.

[The information follows:]

EFFECTIVENESS OF GAUDENZIA HOUSE

While therapeutic community programs such as Gaudenzia tend to have somewhat higher dropout rates than outpatient programs, researchers have found that therapeutic community treatment produces significant, positive change in client functioning. In therapeutic Community studies (including one project involving Gaudenzia), researchers found improvement in mental functioning (i.e., remission of depressive symptoms, reduced anxiety, and other improvements), as well as behavioral changes, including dramatic reductions in, or cessation of, drug use and criminal behavior during the 2 to 5 year post-treatment period.

WHICH DRUG TREATMENTS ARE MOST SUCCESSFUL

The answer to this is complicated by the fact that many drug abusers will have multiple treatment episodes, including different types of treatment. It is not a matter of one short treatment and a cure, but rather like a chronic disease which is managed while the underlying problems receive attention.

We can say that methadone maintenance programs, outpatient drug-free, and residential drug-free programs all work through relapse rates are relatively high. However, based on the latest outcome studies we find that, for clients in treatment at least 90 days in various treatment modalities, between 61 and 77 percent had minimal or no drug use during the year after treatment.

Detoxification, which tends to be a short term treatment with limited objectives, does work, in the sense that a temporary drug-free state and reduction in tolerance is achieved, but for most clients, abstinence is a serious goal only if the client goes into a longer-term treatment program upon completing detoxification.

NIDA has supported a couple of treatment outcome research studies that confirm the effectiveness of these drug treatments. Two previous studies used designs which included follow-up of clients treated in detoxification, methadone maintenance, outpatient drug-free, and residential drug-free programs. The Drug Abuse Reporting Program (DARP), focused largely on opioid addicts across 52 programs entering treatment between 1969–72. The Treatment Outcome Prospective Study (TOPS), examined outcomes for a large sample of opioid and nonopioid clients across 32 programs, entering treatment between 1979–81. Both studies found dramatic decreases in drug use, particularly among those clients who stayed in the treatment programs longer periods of time.

A third study, DATOS, is currently under negotiation and will examine outcomes across drug abuse patterns, treatment program types, and degree of impairment of functioning at admission. The DATOS contract is presently being negotiated, and specific details of the research plan will be unavailable prior to contract award. However, the general design of the study can be described. There will be two phases to the research study: the in-treatment phase and the after-treatment, or follow-up phase. In the in-treatment phase, the contractor will sample from approximately 32 treatment programs representing five different treatment modalities (long- and short-term methadone maintenance, long- and short-term residential treatment, and outpatient drug free treatment). The intake sample should be comprised of approximately 25,000 individuals. During the follow-up phase, the contractor will select approximately 3,500 individuals from the intake sample and will interview them about 6 months after they leave treatment.

At intake, extensive data on the individuals; characteristics and pre-treatment baseline behavior will be gathered including: Demographic variables (age, race, sex, education, income); drug history variables (age at first use, incidence and prevalence of use, patterns of use, problems from use, motivations to continue and to discontinue use, by particular drug types); other outcome variables (criminal activity-type and amount, employment-type and amount); psychological and social functioning (psychiatric diagnosis, social and familial support); treatment history; and other treatment needs (medical problems, legal problems).

The data to be collected during treatment will include extent and pattern of drug use during treatment, what services are received, what the individual's perceptions and expectations of the treatment are, and whether there are changes in psychological, social, health, and other outcome variables (e.g., education, employment, criminal activity).

A follow-up sample will be chosen from the in-treatment intake sample, and will be constructed so that questions about treatment effectiveness may be answered. Data will be obtained for periods of time comparable to those of the pretreatment time periods. Other follow-up variables of interest include historical variables (history of treatment, employment history, drug use history, criminal history) and background variables (e.g., health status, religiosity, and family structure and function).

HOMELESS

Senator SPECTER. All right. I would be very interested to pursue that with you.

Dr. Sullivan, early today Senator Hollings and I met with a group of people in Philadelphia on the homeless. I see someone behind you just gave me the high sign looking for this. I promised

them that I would put to you the same hard questions which they put to us.

And this is in line with a lot of work that Senator Hollings and I have been doing over the years, going back to 1983. I had the honor to Chair the District of Columbia Subcommittee of Appropriations because of my lofty seniority back in 1983, 1984, 1985, and 1986. I then lost out to Senator Harkin, who had less seniority but was in the majority party.

Senator HARKIN. It is a wonderful system.

Senator SPECTER. And I did not mind too much relinquishing the chairmanship to him.

But I thought it would be a very important subcommittee and enjoyed the work on prisons and rehabilitation and with the homeless. We had a very important hearing on the homeless before it became popular to pay attention to the homeless, back in 1983.

And our efforts have led to approbation from Mitch Snyder, which is not too easy to get if you are in Government service.

DRUG PROGRAM FOR HOMELESS

But at any rate, one of the aspects that I think we can tackle with funding through the drug efforts relates to the homeless who have drug dependency problems and alcohol dependency problems. And Secretary Kemp came to Philadelphia several weeks ago, and one of the homeless units which we visited late one Thursday night was an intake center for men.

And I was frankly surprised to see relatively young men, in their twenties, thirties, early forties, who looked to be very able-bodied, who appeared to be functioning reasonably well, but they were drug users and alcohol users and they required detoxification.

So what I did was to ask the people in Philadelphia to put together a pilot project which I said I would submit for a model program if they could structure a program which would be designed to reach relatively young men and women who have alcohol, drug-related problems, who are homeless. And they have come up with a program which I will be passing on to you.

It is a very interesting program. What they are proposing is to have 16 detoxification beds, which require an interval of 5 days. So they can have 73 cycles during a year with 16 beds and treat 1,168 people. And they are looking for 200 therapeutic community residential beds, where the treatment will be approximately 4 months a year.

They are looking for additional section 8 housing, which we are going to have to go to Secretary Kemp for. And they are looking for six permanent counselors, and they are prepared to make a commitment to work this program through on a model cities approach and test for results.

And my question to you is, what do you think of such an approach? And I will talk to you about funding after you answer the first question.

Secretary SULLIVAN. Well, Senator Specter, I think there is no question that homelessness and drug abuse are both serious problems in our society. These problems are much more visible now than they were perhaps 10, 15 years ago. The Department of

Health and Human Services is fully committed to doing everything we can.

I commented to Chairman Harkin a little earlier that the first inter-agency homeless task force has met. Secretary Kemp was elected chairman, and I was elected vice chairman of that task force. We are going to work closely to pool our resources and our efforts to address the problem of homelessness.

The President's budget has requested that the McKinney Act be fully funded, and we are hopeful that the Congress will respond favorably to that request. The President's budget request for drug treatment programs includes $35 million. We want to find treatment programs that would serve as models for the country. We need to evaluate various approaches such as the one proposed in Philadelphia.

Any program we fund should have an evaluation component which measures effectiveness. Perhaps working with your colleagues in Philadelphia will provide us with helpful information.

Senator SPECTER. Well, fine, Dr. Sullivan. I appreciate that response. We will get you the details. We wanted to start early to make the presentation to you because, while there has been some attention, although not enough, to drug addiction as it relates to crime, there has been none on drug addiction as it relates to the homeless.

And I am very interested in the crime problem, but I am also very interested in the homeless problem. And what I would like, to find a time convenient with your schedule for you to make a trip to Pennsylvania. You and I talked about that before.

It is close. You do not have to travel a whole lot of distance to see a whole lot of problems. I know you will want to visit Des Moines at an appropriate time as well. [Laughter.]

But we have already had Secretary Derwinski come to Pennsylvania a few weeks ago. It was not a condition of my supporting him for Department of Veterans Affairs, but he has been there. And the Secretary of Education said last week he would come to Pennsylvania, and you and I have talked about that before.

And I would like to take you to Pittsburg and Philadelphia as a sampler of some of the problems. You know them, but it is enormously helpful when someone of Secretarial stature visits a State. I think there is a lot to be learned and it is quite a boost.

Secretary SULLIVAN. I look forward to that opportunity, Senator Specter. I would certainly welcome a visit to Pennsylvania and look forward to working with you to arrange a date that will be convenient.

You should probably know that one of your citizens, Rev. Leon Sullivan—he is a more famous Sullivan and no relation——

Senator SPECTER. Only temporarily.

Secretary SULLIVAN. He has invited me to address the Opportunity Industrialization Center of America [OIC] conference, I think on May 23, in Philadelphia, and I am looking forward to that.

Senator SPECTER. Well, that might be just fine.

It is hard to become as famous as Dr. Leon Sullivan, but he does not have a budget of $400 billion. [Laughter.]

I want to make one more comment and then ask you one more question. I appreciate the time, Mr. Chairman.

And the comment I want to make is that I am glad to hear you and Secretary Kemp are on this panel of coordination, and I believe that there was an announcement earlier today about a crime program for the District of Columbia and I heartily applaud that. And that is something that Senator Harkin and I have worked on a long time for the District of Columbia, jail, rehabilitation programs.

And I think that Washington, DC, is a good place to start. But I think it is very important that immediate steps be taken to include the rest of America in the crime program and in the program against drugs.

I think it would be unfortunate if America were to conclude that there is a special program because of 535 special citizens, and it is important that those 535 not be considered special, special citizens; that the drug problems are as acute in the ghettoes of Los Angeles and Chicago and Philadelphia as they are in Washington, DC, and that just because Members of Congress have witnessed gun battles and have attracted perhaps a little bit more attention, that we move to take care of the rest of the country.

HEALTH CARE CONTRACT INSOLVENCY

Let me ask you one final question, Dr. Sullivan, about an issue which is somewhat parochial, but very important, and I think it probably has applicability in other places. There has just been in Pennsylvania an insolvency proceeding, a bankruptcy proceeding under chapter 11, involving a corporation named Maxicare Corp., which has a contract with the Commonwealth of Pennsylvania to manage a health insurance program for medical assistance patients.

And they were granted authority to contract the program under a waiver of medical recipient's right of free choice of provider, monitored by the U.S. Department of Health and Human Services, the Health Care Financing Administration.

And the insolvency here has created an enormous problem for many health care agencies in Pennsylvania, amounting to very substantial funds, including the hospital of the University of Pennsylvania. And rather than ask you any question about it now, what I would like to do is I would like to provide this under separate cover to you, if you would review, because it appears to be enormously serious.

And I would not be surprised if this problem has aspects in other States and that this kind of a problem might duplicate itself in other States. So I will supply that to you separately.

Secretary SULLIVAN. Fine, I will be very pleased to review that and respond to you as soon as possible.

[The information follows:]

IMPACT OF MAXICARE BANKRUPTCY

The Penn Health Corporation, a Maxicare subsidiary, administers the HealthPASS program which serves approximately 100,000 Medicaid recipients in south and west Philadelphia. This program operates under the authority of a section 1915(b) freedom of choice waiver.

On March 16, Maxicare filed for bankruptcy and froze all Penn Health assets. Shortly thereafter, as a result of subsequent negotiations between Maxicare, the

Penn Health Corporation and the State, an agreement was reached to pay for claims submitted by providers for services rendered on or after March 1, 1989. However, payments of outstanding claims for services rendered before March 1 have been suspended due to the bankruptcy proceedings.

Pennsylvania has established an escrow account for known amounts owed to Penn Health. This escrow account does not include an as yet unresolved amount from the second year of the contract for the risk limit settlement and certain other costs. This amount cannot be resolved until Penn Health's financial records for that period are audited.

Pennsylvania has announced the selection of a new contractor to operate HealthPASS effective July 1, 1989. The terms of the new contract must be approved by HCFA prior to July 1.

HCFA will continue to ensure that Medicaid recipients have access to necessary medical care and the operation of the waiver is in compliance with Federal law and regulations.

MAXICARE CORP.

Secretary SULLIVAN. The Maxicare Corp. was the largest of the for-profit HMO's, with operations nationwide. I would anticipate that there may be a number of problems around the country, of which this would be only a part.

We will be happy to review that and respond.

Senator SPECTER. Well, I appreciate that. I think your Department needs to take a look at it and see what steps may have to be taken to provide some assistance, because there are a great many medical problems which are now being unattended as so many health providers are recoiling from the financial impact of what has happened.

Thank you very much, Dr. Sullivan.

Secretary SULLIVAN. Thank you.

Senator SPECTER. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Arlen.

I recognize my distinguished colleague, our friend from Hawaii, Senator Inouye.

Senator INOUYE. Thank you very much, Mr. Chairman.

First of all, I would like to join my colleagues in extending to you my best wishes and congratulations on your recent appointment.

Secretary SULLIVAN. Thank you.

Senator INOUYE. I wish you the very best, sir. You have without question one of the most responsible assignments in our Government, and we stand ready to help.

HEALTH OF NATIVE AMERICANS

And this afternoon I would like to ask you questions in my capacity not as a member of this committee, which I am, but as chairman of the Select Committee on Indian Affairs. I have had this assignment now for over 2 years as chairman and the picture that has unfolded of the health conditions of native Americans is at best a disgrace to this country and at worst a disaster.

For example, in the area of suicides among young men, say between the ages of 20 and 24, in the native American population it is eight times the national norm. For young men in Alaska, Alaskan Indians, the native Americans in Alaska, it is 18 times the national norm.

The rate of alcoholism coincidentally is the same, about eight times the national norm for the native American population and about 20 times in Alaska for the Alaskan population.

And when we look at diseases, and I am not talking about the exotic ones, but stuff like diabetes, they are No. 1 in the Nation. They are three times the national norm. When we speak of respiratory diseases, they are the worst in the Nation. Cancer, you name it, they are on the list there.

And I think that by the Constitution and by the laws of this land there is a special relationship that exists between our country and Indian nations. Indian nations and Indian people are sovereign. I realize it is very difficult for most Americans to realize this, but they are sovereign. It is by the history of these United States.

In fact, as part of this sovereign relationship we entered into 800 treaties with Indian nations over the years, and this is a footnote in history. Of the 800 treaties, this Senate of ours—and Senators Harkin, Specter, and I are the successors—this Senate refused to even consider 370 of them. It is in the files somewhere. No hearings were held, but we insisted that the Indians live up to their promises.

Of the 430 that we ratified, we violated provisions in every one of them, no exceptions. I mean, it was complete. They began with the recognition on the part of the Government of the United States as having title in over 550 million acres of land. Today they have jurisdiction over 50 million.

Something happened along the way. We had the movement of our people westward, and whenever they found gold or good things in the mountains, out went the Indians. And the story is a dismal one.

Anthropologists suggest that 200 years ago there were at least 10 million Indians residing in the 48 States, the lower 48. At the end of the Indian wars, which came about about 130 years ago when by national policy we decided that all the Indians had to move west of the Mississippi and further as we moved westward, we decimated the Indians. And at the end of that war there were approximately, according to experts, somewhere in the vicinity of 250,000 to 500,000 Indians remaining. We did a good job in slaughtering them.

Now, I think there is a special trust relationship that exists by law, and I am sorry to say that we have not kept up.

Now for example, my question, the first one, sensing the budgetary constraints that you have to live under and all of us have to live under, all that I requested of the Indian Health Service was to maintain the 1988 programs at the 1988 rate.

INDIAN HEALTH SERVICE RESCISSION

I did not ask for any increases, even if the increases were fully justified. But then I notice in response to that, with all the shortfall in funds for this fiscal year, your Department has submitted for approval a rescission request of $12 million in the Indian Health Service.

Of all places we need the money, they picked on the Indian Health Service. And I can understand this, because up until recently very few members cared about this. In fact, it may be of interest

to you, I got on this committee because there was a vacancy that nobody wanted to fill. And the leadership said: How about you getting on the committee? And I said: Why me? I don't have any reservations in Hawaii.

They said: At least you look like one. [Laughter.]

We laugh about this, but that was the way I got on. But I am chairman now and I am going to see to it that something is done about this. It is a disgrace.

And I would like to submit a few questions, sir. Those questions were supposed to have been submitted by you, but I did my best to return here so that I could personally bring to your attention the plight of the Indians.

Just a casual study should sicken anyone. And these are the first people who resided here, long before your ancestors or mine ever thought about coming here, in your case involuntarily. And I think there is a special obligation we have to at least carry out this trust responsibility.

And I would hope that your administration will look very carefully into the problems of the native Americans. I would appreciate that.

Secretary SULLIVAN. Thank you, Senator Inouye. Thank you for your kind remarks, and for expressing your concerns about the health status of native Americans.

I will give this special attention. This is not a new-found interest on my part. In July of last year as a member of the National Cancer Advisory Board at NIH, I visited all of the major Hawaiian Islands to meet with members of A Ola May, the native Hawaiian health professions group, to discuss cancer in the native Hawaiian population. I spent almost 2 weeks there. The data concerning the incidence of cancer and the death rates indicate that they are the highest of any population group.

This visit was occasioned because at that time on the National Cancer Advisory Board I was chairing an effort that was called the National Black Leadership Initiative on Cancer. We organized a program to look at cancer in the black population by visiting eight metropolitan areas in this country. The purpose of these visits was to bring this issue to the attention of the public, because many of these things are not widely known.

This effort was successful because of the knowledge of the native Hawaiian population gained through the offices of Dr. McKay of the National Institutes of Health.

In my comments made both prior to my confirmation as well as in visits, made to various facilities of Health and Human Services, I have emphasized my interest in the health problems of our minority populations, including the native American population.

These problems can be addressed and I think addressed effectively, as indicated by the fact that we have done a good job on infant mortality in the native American population. That is a result of installation of case management approaches for pregnant women in the native American population. As a result of that, the infant mortality rates, which were once among the highest of any group, have now fallen quite remarkably and are around 9.8 infant deaths per 1,000 live births, which is comparable to that of the white pop-

ulation. We know that with appropriate provision of services, many of these problems can be diminished.

Of interest, too, is the fact that many of the same violations of treaties apparently occurred in Hawaii, with the native Hawaiian population when they became a territory of the United States.

While these health statistics were quite dramatic, I was struck by the fact that among the native Hawaiians their No. 1 problem was recovery of lands which they felt had been unfairly and unlawfully taken away. Their premise was that to regain good health and social stability, et cetera, they first needed to address the problem of land.

We will be looking at these programs and doing everything we can to address them within the purview of health and human services.

Senator INOUYE. Mr. Chairman, I appreciate the sensitivity demonstrated by the Secretary. I forgot to give you a little footnote. I believe I said that 200 years ago there were approximately 10 million Indians living in the 48 States. Today there are approximately 2 million. The population has gone up from 500,000 to 2 million now.

As a matter of interest, during the Indian wars the Surgeon General of the United States, the U.S. Army, was a scientist of sorts, and he was then conducting a survey that was rather in vogue, to see the correlation between cranial capacity size and intellect.

And so he wanted to measure the intellect of American Indians. So he sent word to the officers and the men in the field, and there is a copy of that letter in the Archives, telling them that he is in the process of making a study of the cranial capacity of American Indians, it would be most helpful in this survey and study if they could send skeletal remains.

Well, the soldiers, the officers, and men, did a good job. They went around digging up graves and gathering up bodies from battlefields. And it got to a point where the Army said, well, we have got enough, so they sent all the skulls to the Smithsonian.

We have no idea how many skulls the Army did collect, but of interest to some of us on the committee, today in the Smithsonian collection there are over 14,500 skulls and skeletal remains of American Indians, plus 4,000 of Alaskans.

It just occurred to me, I wonder how people would take it if we had a museum with 14,500 skulls of Irishmen or Frenchmen? We have got a collection here of 14,500.

Senator HARKIN. What are they going to do about it? That is shocking.

Senator INOUYE. That is us.

Senator HARKIN. That is amazing. Are they going to return them? Is there any way that they can be returned for proper burial?

Senator INOUYE. Well, they say they need this for anthropological purposes, studies. Slowly we are now in the process of returning some, those that can be identified, because the Indians want to give their people a decent burial.

You see, if they dug your grandfather's grave it is grave-robbing. For the Indians, it was scientific research.

Senator HARKIN. Amazing.

Senator INOUYE. I think this attitude should change, do you not think so?

Secretary SULLIVAN. This is rather shocking. I was not aware of this; that is a level of insensitivity that is hard to explain.

Senator INOUYE. Well, it has changed now, but that was the official policy of the United States not too long ago. Maybe the time is here to rectify this.

So I hope you can disregard your rescission request for the $12 million.

Secretary SULLIVAN. We will certainly review that, Senator Inouye.

AZT FUNDING

Senator HARKIN. Thank you very much.

Senator INOUYE. Thank you very much.

Senator HARKIN. Dr. Sullivan, a couple of other things here. Who is going to pay for AZT? There have been several emergency appropriations—$30 million, $10 million, $5 million, and a second reprogramming a week ago last Friday.

No other drug for any other disease is provided free by the Federal government. Currently more than 7,000 AIDS patients depend on this Government funding. Another 30,000 AIDS patients have AZT paid by Medicaid, private insurance, or by themselves.

We hear from NIH that it may soon be recommended that all HIV-positive people start using AZT before they actually contract AIDS. This could cost $1 billion a year.

Have you given any thought as to where we are headed with AZT? And this could be upon us very shortly. I understand that just during this administration we are going to have 270,000 additional AIDS cases within the next 3 years.

Secretary SULLIVAN. This is one of the serious aspects of the whole problem of HIV infection in our population, Senator Harkin. We received a letter from some Members of Congress encouraging us to transfer $5 million, in addition to the $10 million which had been done earlier.

We transferred the money with the understanding and the hope that the States would by the end of this current fiscal year provide the funding for AZT therapy through the regular channels. While we certainly recognize and are sensitive to the problems that exist with those individuals receiving AZT, we had to take this $5 million from other programs.

We are not comfortable in doing that, but we had to respond to that need. We are hoping that the Congress will provide another mechanism so that we do not have to take funds away from our research and education effort.

It is important that our research and education efforts proceed vigorously so that our scientists and health educators will have the resources they need both for new research breakthroughs as well as continued education of our population as to how the AIDS virus is spread.

Senator HARKIN. When you mention new mechanisms, what does that mean? Forty percent of AIDS patients are now eligible for Medicaid, so when you say a new mechanism, are you talking

about some new entitlement program that would entitle AIDS patients to AZT?

Secretary SULLIVAN. Just what the mechanism might be, I am not prepared to say. I was responding primarily to the reality that thus far AZT therapy funding has come out of the research and education budgets. We feel that is an inappropriate use of those funds.

Ultimately our approach is to find a cure for AIDS. As we take away from our research funds, we worry that we may be delaying our efforts to find a cure. Funding through Medicaid is one mechanism, but whether that is the best mechanism is questionable. There is going to be significant expansion of the need for AZT or other drugs. We do not want to neglect the other areas of our Medicaid program.

It will require either additional funds through that program or through another program. I am not prepared to say at this time just what that would be.

RELATIVE VALUE SCALE

Senator HARKIN. Medicare part B expenditures have been rising, 18 percent since 1984. The Physicians Review Commission is working on a national cost-based relative value program which is going to try to even out the payments among specialties and across geographic areas.

Are you supportive of this relative value scale, enactment of the relative value scale?

Secretary SULLIVAN. Yes, I am, Senator Harkin. It is very clear to most observers of our present payment systems that we have been driven by procedurally oriented payment mechanisms and have not given sufficient recognition or weighting to the cognitive-based areas.

Pediatrics, for example, happens to be a specialty to which we entrust the future health of our children; and therefore, in terms of productive years of growth, development, and optimal development there is no other specialty that has that kind of responsibility. Yet, overall pediatricians are among the lowest paid of the various specialists.

We feel that activities such as the relative value scale are performing a good service because the value for the services, as we currently pay for them, is not appropriately balanced in terms of their value to society.

RURAL HEALTH AND SAFETY

Senator HARKIN. Mr. Secretary, I just have two quick questions both having to do with rural health and safety. We know that agriculture has the second highest occupational fatality rate in the Nation. About 90,000 disabling injuries occur each year and 300 children are killed each year in farming accidents.

Studies done by the Centers for Disease Control found a disproportionate share of injuries and disease associated with chemical, biological, and physical hazards. This morning I had a group in from Iowa and we happened to be talking about this, and one of the individuals said they had four young people within 1 square

mile, who lived within 1 square mile of each other, who died of cancer before they graduated from high school, within 1 square mile.

We know that the incidence for cancer among farmers is very high. I think it is one of the highest among all occupations, if not the highest.

It would seem to me that the Centers for Disease Control is in a unique position to lead a comprehensive national effort to prevent injury and disease in agricultural and rural areas and look at this whole health problem associated with chemical, biological, and physical hazards in agriculture.

I am just again asking you, if you would take a look at this, see if we might direct the Centers for Disease Control to take a look at this as a target project.

Secretary SULLIVAN. Yes, Senator Harkin; we would be happy to do so. As I have pointed out previously, one of the major thrusts of my administration is going to be increased emphasis on prevention. I think this falls into that area.

We will be happy to review our data and see what additional things we ought to be doing, and try and put those in place to address this problem.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I appreciate that very much, Mr. Secretary. And that is really about it. I have a lot of other questions I will submit to you in writing.

Secretary SULLIVAN. Fine. We will be happy to respond to you.

Senator HARKIN. OK. Thank you, Mr. Secretary.

Secretary SULLIVAN. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

UNREALISTIC CUTS

Question. Your budget proposes $1.4 billion in cuts virtually all of which have been proposed in previous years, and rejected by Congress. The biggest cuts are aimed at programs serving the most impoverished, vulnerable persons in our society. Here are some examples:

Community Services	-$381 million
Energy Assistance for Poor	-283 million
Health Professions	-211 million
Refugee Assistance	-140 million
IV Drug Treatment Grants	-50 million
National Institute of Occupational Safety and Health	-26 million
National Health Service Corps	-20 million
	- $1,111 million

I have a hard time reconciling these cuts with the rhetoric of your prepared statement, which outlines the hopes and aspirations of the President for a "kinder, gentler" America.

Why is it that you only talk about the areas where you are proposing increases, while being absolutely silent about the unrealistic cuts your are proposing to finance them?

Answer. In President Bush's budget submission "Building a Better America", he highlights areas of priority with the budget amounts for these programs. The remaining programs, not highlighted, have been designated as being in the "residual freeze" category. For IV treatment grants the apparent reduction of $50 million is not a cut, but provides the balance of an one-time authorization of $100 million ($75 million in FY 1989 and $25 million in FY 1990).

The President has expressed his hope, and I fully agree with this ambition, that the Congress and the Executive Branch will negotiate a budget compromise on the programs in the "residual freeze" category.

By law we are required to meet the deficit target in the Gramm-Rudman-Hollings bill of $100 billion. To meet this target many hard choices about programs will have to be made, and together we can make them.

Question. Do you really expect Congress to make these cuts to pay for the increases you are proposing for Head Start, AIDS research, and drug initiatives?

Answer. I sincerely hope that the Administration and Congress can reach an agreement on funding that will enable us to meet the deficit reductions required by law.

Together we must prioritize programs and provide the funding to those programs based on mutually agreed upon priorities. Some worthwhile programs may not be funded at levels that we would like,

but we must gain control of the deficit, or face an even greater dilemma in the future.

REDUCED FUNDING EFFECT ON SERVICES

Question. Mr. Secretary, I need not tell you that there are many crucial services that your Department provides. And, you are also aware of the huge budget deficits which need to be reduced. Funds are going to be very limited in the coming fiscal year. At the same time, I am hopeful that we can find efficiencies to reduce costs without cutting services. Nevertheless, we need to be aware that it may even be necessary to reduce the level of services.

Can we have your cooperation and the cooperation of your staff in finding ways to hold down this budget?

Answer. I know I speak for all the employees in HHS when I categorically say that we will do all in our power to cooperate with the Congress. I have not been in office long, but I plan to look for ways to manage HHS without diminishing services as I learn more about the Department.

The programs in HHS affect the lives of one of every four Americans, among them those who need us the most — the sick, aged, and the poor. However, in our efforts to aid all the citizens who need our assistance, we must be prudent and exercise control to allow us to balance the budget.

The first step in this is to meet the FY 1990 Gramm-Rudman-Hollings deficit target of $100 billion. In addition, it is incumbent on each employee to ensure that productivity increases, and that the services provided are of the highest caliber at the least cost. The Office of the Inspector General keeps a vigilant watch on activities within the Department to assure that these goals are met.

OUTLAY OF DRUG BLOCK GRANTS

Question. Major funding for the fight against drugs comes from the Alcohol, Drug Abuse, and Mental Health Services block grant. The committee provided over $805 million for the ADMS block grant in FY 1989. Were six months into the year already, yet I understand that less than $300 million has gone out to the States. What is the problem? How is your Department working with States to get these funds moving?

Answer. As of April 13, 1989, 35 States have been awarded 75 percent of their total FY 1989 ADAMHA block Grant allotments. This totals $441 million. These States will receive their final allotments ($147 million) on July 3, 1989. Of the remaining $217 million, $40 million is set-aside for data collection, technical assistance, and services research activities and $177 million will fund the 15 States, the District of Columbia, Puerto Rico, and other territories whose applications have either not yet been received (7 States and the District of Columbia) or are being reviewed and/or revised.

Question. What can we do to get funds into the pipeline?

Answer. The Department cannot set application deadlines nor mandate a State to file its block grant application. We can, and do, expedite the flow of these funds through timely notices of funds availability, technical assistance to the States and through expedited application review. To the extent feasible, we have done all three.

Question. What's going on? What is the Department doing to move these funds?

Answer. The Department is in no way inhibiting the States expenditure of FY 1987 or FY 1988 Alcohol and Drug Abuse Treatment and Rehabilitation (ADTR) block grant funds. All funds were obligated to the States by the close of each respective fiscal year (9-30-87 and 9-30-88). As of April 1, 1989, States have expended a total of $149 million of the $163 million made available to them in 1987 and $63 million of the $160 million in 1988 funds. We believe the delay in expending these funds is, in part, in response to the 1987 funds being appropriated very late in the fiscal year and the fact that Congress articulated that these were one-time funds. Also, ADTR was a new program and often States need time to respond to new programs. The spending cycles of States continue to lag behind the Federal funding cycle by over a year more than is generally expected, however, this is not out of line with other Block grant program.

Question. What are your suggestions to get the 1989 money out?

Answer. As of April 13, 1989, 35 States have received the block grant allotments. We anticipate that the 8 States and Puerto Rico, whose applications are either under review or being revised, will receive their awards soon as well. Should the remaining 7 States and the District of Columbia file their applications soon, we believe the States will be able to obligate their funds by September 30, 1989.

Question. Has the Department got a mechanism yet for granting waivers?

Answer. As of this date, we can give the Congress a status report on the Guidelines for ADAMHA Block Grant IV Drug Abuse Waiver:

—The Administrator of ADAMHA has been delegated the authority to review and grant a State's request for a waiver of the 50 percent set-aside for IV drug abuse (section 2023 of the Anti-Drug Abuse Act of 1988, P.L. 100-690).

—The guidelines for application for a waiver were prepared by the Office of Communications and External Affairs, ADAMHA.

—The guidelines were approved by the Public Health Service on April 13, 1989 and forwarded to the Office of Management and Budget on April 20, 1989.

—Upon approval of the guidelines, ADAMHA will notify each State by mail of the waiver process.

—A decision on each request for waiver will be made no later than 120 days after the request is received.

Question. Is your Department willing to work with the Congress to grant States more flexibility in allocating block grant funds?

Answer. I would be happy to cooperate with the Congress to grant States more flexibility in spending their block grant allotments.

CATASTROPHIC HEALTH INSURANCE

Question. Do you feel the amounts included to carry out the Catastrophic Health law are adequate?

Answer. Despite the necessity for restraint and careful fiscal management, we are confident that HCFA has been provided adequate resources in the FY 1990 budget to implement the new Catastrophic Health Insurance program and to carry out its regular program responsibilities. The implementation of the CHI program is a major priority of the Department, and we have included just over $300 million for this purpose.

Question. Mr. Sullivan, are you helping to educate the public about the new catastrophic health legislation?

Answer. We have taken a number of actions to inform and educate beneficiaries. Specifically, a 15 page "Medicare Has Improved" pamphlet was mailed to all beneficiaries in October 1988. Press kits were distributed to all major newspapers. The revised 1989 Medicare Handbook contains a description of the Catastrophic benefits and financing procedures. This handbook has been distributed to all Medicare beneficiaries. A Medicare training video has been distributed to regional offices, SSA offices, contractors, area agencies on aging, and beneficiary organizations.

Question. What's being done to inform senior citizens about their costs and benefits under the law?

Answer. HCFA works on an ongoing basis with organizations representing the elderly and Medicare beneficiaries to help them inform their membership of the provisions of the Catastrophic Health Insurance program. Two national CHI hotlines had received about 300,000 calls as of the end of March. Subjects included status of claims, premiums and deductibles, Medicare coverage, and the supplemental premium. Written inquiries have average over 500 per month. Subjects include Part B reimbursement, Medicare coverage, home health benefits, and the supplemental premium.

MEDICAL PROCEDURES CONTROL

Question. What steps are you proposing to control the volume of medical procedures?

Answer. We are concerned about the volume of Medicare services per beneficiary because it accounts for approximately half of the annual 15% increase in Medicare Part B expenditures. In response to

a Congressional mandate, we are currently preparing a report to Congress on volume of medical procedures. In that report, we are examining approaches currently used to control volume as well as possible alternative approaches. We expect to transmit that report to the Congress this Spring.

Additionally, the Department is reviewing the Physician Payment Review Commission's recommendation that expenditure targets accompany any movement toward a relative-value based fee schedule.

MEDICARE CONTRACTORS

Question. Are you aware that this cut would force layoffs of 2,000 Medicare Contractor personnel including 1,110 auditors?

Answer. We are aware that the reduction in payment safeguards could lead to a reduction in Medicare contractor staffing levels. Lay offs would most likely occur among personnel who carry out discretionary activities such as field audits, while staff would be retained for mandatory functions such as claims processing and audits of provider cost reports. However, contractors do have the flexibility to decide how to distribute their workloads.

Question. Would you support efforts to achieve savings by reducing duplication and overlap in Medicare contractors' computer operations?

Answer. Currently about 40 percent of our contractors are involved in various forms of standard systems which are designed to reduce duplication in Medicare contractors' computer operations. The HCFA approach to standard systems is based on two themes: shared maintenance and standard modules. Under shared maintenance, a group of contractors using or acquiring the same base processing system share the costs and centralize the work for changes to the system's application programs. HCFA support for systems acquisitions and installation costs is in large part contingent on the contractor actively seeking a solution to its systems problem which includes shared maintenance. Standard modules are used for certain claims processing functions that require the use of a standard method (e.g., Part A pricing and Medicare Secondary Payer payment calculations). Standard modules are given to all contractors for incorporation into their individual systems.

In FY 1990 promotions of standard systems will continue with particular emphasis on expanding use of the Part B Standard System developed in FY 1988.

AZT FUNDING

Question. Who will pay for AZT?

Answer. As we stated in our request to transfer funds from PHS AIDS accounts to pay for the provision of AZT, it is our expectation that the next 6 months will allow time for each State working with private insurers to develop strategies for providing AZT to its citizenry in need. Currently, AZT is a reimbursable drug under Medicaid and all States, except Colorado and Alabama, cover its reimbursement for those individuals eligible for Medicaid.

CENTERS FOR DISEASE CONTROL

Question. Mr. Secretary, I am sure you know that agriculture has the second highest occupational fatality rate in the Nation. About 90,000 disabling injuries occur each year and 300 children are killed each year in farming accidents. Studies done by the Centers for Disease Control have found disproportionate share of injuries and disease associated with numerous chemical, biological, and physical hazards.

Mr. Secretary, any one who has grown up on a farm or lived in a farming community can tell you that they have a father, brother, uncle, child, or neighbor, that has been seriously injured or died in a farming accident. I think that it is apparent that rural health and safety is a huge problem. A problem that we have not, as yet, addressed.

It would appear that the Centers for Disease Control is in a unique position as the only Federal agency engaged in activities covering all injury and disease areas, to lead a comprehensive national effort to prevent injury and disease in agriculture.

Could the Centers for Disease Control launch such a program if funding were made available?

Answer. CDC, through its National Institute for Occupational Safety and Health (NIOSH), is already active in health and safety concerns for agricultural workers. In 1989, NIOSH expects to spend about $1.2 million on the prevention and control of workplace illness and injury for farmers and farm workers. CDC has the relevant expertise to conduct such activities.

Question. Mr. Secretary, do you feel such an initiative is needed?

Answer. The prevention of all types of injuries is a major initiative of the PHS as it establishes its health goals and objectives for the Year 2000. While agricultural worker health and safety has not been specifically earmarked within the 1990 President's budget as a priority for additional funding, CDC has several projects underway targeted on this issue.

Question. Mr. Secretary, will you work with the Subcommittee to address this problem?

Answer. The Department is prepared to work with the Subcommittee to address any specific concerns it may have in this area.

RURAL HEALTH CARE

Question. Please explain to me exactly what is this Administration's commitment to rural health care?

Answer. We are very concerned about access to care for beneficiaries who live in rural areas. For this reason, HHS is funding numerous projects to provide significant resources for rural economic development in the health sector. However, we

recognize that the problems facing rural hospitals are complex and Medicare should not be viewed as the sole means of viability for these hospitals.

The Department has established an Office of Rural Health Policy (ORHP) within the Health Resources and Services Administration within the Public Health Service. ORHP supports five Rural Health Research Centers around the nation, and works with other Federal agencies, States, national associations, foundations and private sector organizations to seek solutions to health care problems in rural communities. The 1990 budget includes $3.1 million for ORHP, more than doubling the 1989 level of $1.4 million.

In the past few years, major changes to the Prospective Payment System have been enacted to assist rural hospitals including differential payment updates in FY 1988 and FY 1989, differential offsets for outliers, a new methodology for calculating basic rates that resulted in increased rates for rural hospitals, revised standards for determining which counties are rural and urban, regional floors in the payment rate for hospitals in regions where the regional rate is greater than the national rate, revision of the swing bed program to allow participation by hospitals with 50 to 100 beds, and set-asides for rural research and demonstration projects.

To increase the availability of primary care in rural areas, the rural health clinics program provides that Medicare and Medicaid payments can be made to the nearly 460 rural health clinics where nurse practitioners and physicians assistants furnish care without the direct supervision of a physician.

The Public Health Service has a number of programs directed toward the development of health care resources in rural America. Approximately half of 600 Community and Migrant Health Centers are located in rural regions of the country. The National Health Service Corps ($20 million in 1990) will continue to support health care providers in over 800 underserved areas, encouraging providers to remain in rural locations after their term of service in the Corps have ended.

AIDS RESEARCH FUNDING

Question. Do you expect to see research funding for AIDS starting to level off?

Answer. The rate of increase for AIDS research funding has already begun to slow within the Public Health Service. From 1986-1987, funding increased by 115%; from 1987-1988 by 92%; from 1988-1989 by 34%, and under the FY 1990 request, from 1989-1990 by 24%. I expect this downward trend in the rate of increase to continue, although I expect the level of funding for AIDS to remain high.

Question. What for example do you expect the request next year to be for AIDS research?

Answer. I cannot answer that question at this time, but I assure you I will examine this issue carefully as I review agency requests for FY 1991.

Question. According to the Inspector General, most of the growth in individual research projects is due to salary growth. On average NIH funded researchers got on average an 11.3 per cent salary increase in 1988. Mr. Secretary, what should we do about this problem? You have proposed to cap university salaries at $120,000. Is this cap too high?

Answer. The proposed $120,000 cap is designed to slow the rate of growth of the cost of biomedical research. It will limit the rate of reimbursement for salaries charged to NIH grants and contracts, but will not limit the total salaries actually paid by universities. This proposal does not impinge on the capacity of a university to establish its own pay scales at levels higher than $120,000.

LOW MORALE AMONG HHS EMPLOYEES

Question. When the Office of Personnel Management surveyed morale problems at major Federal agencies, it voted your Department near the bottom — number 20 on a list of 22.

Do you find it acceptable to head the biggest Department in government — the "people's programs" of our society — whose workers have one of the lowest job satisfaction records?

Answer. The survey you refer to was a special study conducted by the U.S. Merit Systems Protection Board in 1986. Their final report, entitled "Working for the Federal Government: Job Satisfaction and Federal Employees", was issued to the President and the Congress in October 1987. Based on individual agency responses to two of the 64 questions asked in the survey ("In general, I am satisfied with my job" and "In general, I like working here"), HHS was "ranked" 20th out of the 22 agencies included in the survey, in terms of overall job satisfaction.

Secretary Sullivan has made it very clear that one of his top priorities as HHS Secretary will be to improve the quality of work life for the more than 100,000 dedicated and concerned employees of the Department — or, to phrase it another way, to put a human face on the workplace. Since his swearing in on March 10, he has already taken several steps to foster increased job satisfaction among his employees.

The first of these steps was the establishment on March 22 of a new Employee of the Month Honor Awards Program. Each month, Secretary Sullivan, along with his senior staff, will personally recognize non-supervisory employees from throughout the Department for exemplary acts and services.

As a second step, Secretary Sullivan plans to launch a comprehensive, Department-wide Employee Morale Initiative in the near future. This initiative will address several major areas of concern to the Secretary, including:

- o improving communications with HHS employees;
- o enhancing the Department's awards and recognition programs;
- o promoting employee health and wellness;
- o offering more comprehensive benefits assistance and services;
- o expanding training and development opportunities; and
- o improving the physical environment in the Department's many facilities.

Secretary Sullivan intends to remain personally involved as this Initiative progresses, as well as to personally involve HHS employees. It is his hope that these activities, along with several other grass roots efforts already underway in various parts of the Department, will have a positive impact on employee job satisfaction.

As a final note, certain factors which are not under HHS control and which can be changed only through the legislative process — most notably, employee pay and benefits — may have contributed significantly to the negative survey results.

SOCIAL SECURITY STAFF MORALE

Question. The General Accounting Office has just issued a report detailing massive morale problems among personnel at Social Security offices, primarily due to the loss of 15,000 jobs over the last 5 years. Yet, you are proposing further cuts of 2,000 more jobs in fiscal 1990. Aren't you concerned about forcing dedicated employees out of this agency, which can only lead to deterioration of services to the elderly and the handicapped?

Answer. There is no evidence to suggest that SSA's level of service has deteriorated during the "downsizing" of the past 5 years. In fact, independent audits of service have indicated that service has been maintained or improved during that period.

After FY 1990, we plan to stabilize employment, consistent with workloads and productivity. We believe this stability will help employee morale.

ADMINISTRATIVE LAW JUDGES

Question. On January 8, 1989, an article appeared in the New York Times entitled "Judges Who Decide Social Security Claims Say Agency Goads Them to Deny Benefits", reported that many Administrative Law Judges within the Social Security Administration are being pressured to keep costs down by imposing monthly quotas of cases which a judge must complete and by maltreating judges who award benefits which appear to be excessive. Are you aware of these allegations and do you believe that this problem exists within the Social Security Administration?

Answer. It has never been a policy of HHS to set quotas for dispositions or reversal rates for Administrative Law Judges (ALJ). This is substantiated in the case of Nash v. Bowen (March 7, 1989). The Court of Appeals for the Second Circuit has issued a decision which gives the Social Security Administration, Office of Hearings and Appeals substantial latitude to institute programs to improve the efficiency of its ALJ's. The court noted that "in view of the significant backlog of cases, it was not unreasonable to expect

ALJ's to perform at minimally acceptable levels of efficiency." The court also found that reversal rates were only used to determine whether a given ALJ was using improper adjudicatory methods and not to coerce fewer reversals.

GENE MAPPING PROJECT BENEFITS

Question. The committee has been told by scientists around the country that they support the gene mapping project, but only if it won't detract from more target research. Do you believe the benefits — somewhat unknown at this time — will be worth the expenditure?

Answer. Our current state of scientific knowledge and the rapid pace of technical advances provide ideal conditions for pursing the human genome project. The proposed research plan and resources identified for this activity are appropriate given the potential for significant advances in a number of areas.

AIDS FUNDING

Question. Since the beginning of the epidemic there have been 89,671 cases of AIDS reported; during the Bush administration, based on statistical trend, the Department expects 275,00 additional people to contract AIDS. Is the health delivery system across the country prepared to handle the increase?

Answer. In response to the President's Commission on the HIV epidemic, we are undertaking an evaluation of our current system of health care financing and will explore various policies for filling in the gaps in eligibility and coverage.

Question. The Department has not requested any funding for the new AIDS treatment block grant authorized at $100 million for fiscal year 1990. What role do you see for Federal funding for the treatment of AIDS patients?

Answer. You may recall that authorization for the AIDS treatment block grant did not occur until well after the Department had submitted its FY 1990 budget request to OMB. This is one alternative I expect I will weigh as the Department develops its FY 1991 budget.

HEALTH SYSTEM ASSESSMENT

Question. Mr. Secretary, do we need to reassess our public health system and its response to the health prevention and care needs of the country?

Answer. I have consistently stated that one of my goals as Secretary is to advance the emphasis on disease prevention and health promotion. Through the prevention focus this Nation can attain vast improvements in health status. The Institute of Medicine (IOM) report on the "Future of Public Health" underscores the importance of the work of the Centers for Disease Control in public health capacity building at the State and local levels. A key project facing the Nation is establishing health

objectives that can be addressed by State and local public health agencies. This Department will be working with States and communities to develop these objectives, following the lead of the National Health Objectives for the year 2000. The IOM has challenged the public health professionals, a challenge which the CDC intends to meet by developing data systems to measure health status and monitor achievement of the year 2000 objectives.

NURSING SHORTAGE

Question. What role do you intend to have the Department play in responding to the current nurse shortage?

Answer. As you know the Commission on Nursing placed much of the onus of the nursing shortage on the private sector medical institutions and on the nursing profession itself. Nonetheless, there are opportunities for us to provide guidance and support to the efforts of the medical community. This we will continue to do through the National Center for Nursing Research, the Division of Nursing in the Health Resources and Services Administration, and the Nursing Student Loan program.

Question. Which of the recommendations of the Secretary's Commission on Nursing will the Department be implementing immediately?

Answer. As part of efforts to guide and assist the medical community address the nursing shortage, we will continue to support research on the nursing profession through the National Center for Nursing Research (NCNR). The NCNR and HRSA's Division of Nursing will also continue to support and host national conferences which address nurse utilization and other professional concerns.

In addition, the Health Care Financing Administration is in the process of evaluating the impact of Medicare reimbursement under the Prospective Payment System on nurse compensation.

We will also continue to support nursing students through the Nursing Student Loan (NSL) program. In both 1989 and 1990, we expect over 11,000 students to receive up to $4,000 in financial assistance through this program.

Question. What are the priority nursing research areas you will work to fund at the National Center for Nursing Research?

Answer. Among other priorities, NCNR will emphasize prevention and care of low birth-weight infants; nursing care of AIDS patients and their partners and families; and care giving issues, especially issues related to those who care for Alzheimer's patients.

VACANCIES IN TOP JOBS

Question. Mr. Secretary, we are about to conduct detailed appropriations hearings with the major component agencies of your Department, but it appears the witnesses will be "acting" holdovers from the Reagan administration.

When do you expect to have your team of assistant secretaries and major agency heads in place?

Answer. Of the top positions within the Office of the Secretary, two are awaiting confirmation by the Senate. One additional nomination is expected to be submitted to the Senate by the White House momentarily. One appointment not requiring confirmation has been made. Two nominations and two appointments are in process at this time.

For the Department as a whole, two nominations to head Operating Divisions are awaiting Senate hearings, and the others are expected to have nominations made by the President very soon.

The appointments and nominations which have not been made are progressing satisfactorily, and all of these top positions are expected to be filled by this summer.

Question. Have you made your selections yet, and just await White House action?

Answer. Among the top positions in the Office of the Secretary, as of April 17 there were two appointments which had been forwarded to the Senate for confirmation (Under Secretary and Assistant Secretary for Public Affairs) and one nomination ready for submission to the Senate by the White House (Assistant Secretary for Legislation). In addition, the appointment of the Director of the Office for Civil Rights has been made by the Secretary. Nominations by the President will be made presently for the General Counsel and the Assistant Secretary for Planning and Evaluation. Appointments for the positions of Assistant Secretary for Management and Budget and Deputy Under Secretary should be made shortly. We are working closely with the White House to complete our executive team.

Question. What is your view on Federal support for nursing education?

Answer. I am in favor of maintaining the Nursing Student Loan program and continuing indirect support through Medicare medical education payments to hospitals as well as continued support for the training of nurse-scientists through the NRSA program.

NATIONAL HEALTH SERVICE CORPS

Question. Knowing the Administration's proposal to cut Corps funding in half (from $40 million to $20 million) was made before your tenure, can you justify this proposed cut, or would you prefer to re-examine this request?

Answer. As with health manpower programs, I am in the process of examining the National Health Service Corps, the 1990 request for the program, and what changes, if any, should be made within the context of our budgetary constraints.

Question. Would you agree to examine the need for replacement assignments to Iowa? The National Health Service Corps doctors we have now are a great help, and they're providing services to people who would go unserved otherwise.

Answer. I am sympathetic with your interest in retaining the services of NHSC obligors. I will ask the Health Resources and Services Administration to review your concerns.

Question. What is the status of the nursing loans mandated by Congress in FY 1989 — How many loans have been made, and what funds have been expended so far?

Answer. In 1989, as part of the NHSC loan repayment program, the Committees directed HRSA to make loan repayment agreements available to nurses. HRSA has done so, however, to date, nurses have shown little interest in the program and no agreements have been made.

DRUG ABUSE COORDINATION EFFORTS

Question. Have you met with Secretary Bennett to decide how your Department will work with the drug czar to coordinate anti-drug abuse efforts?

Answer. Yes. I have met with Secretary Bennett and we have begun discussions on the coordination of the government-wide effort to address this national problem.

Question. In terms of our efforts in research, treatment, and prevention, do we have our priorities straight? Are we neglecting alcohol while placing the emphasis on drugs?

Answer. I agree with you that alcohol abuse and alcoholism are problems of national significance. I believe that the Congress and Administration have recognized this and both of the recent Anti-Drug Abuse Acts (1986 and 1988) have included specific additional resources for research on alcohol abuse. Funds available for prevention and treatment generally cover all substance abuse, including alcohol.

OCCUPATIONAL SAFETY REDUCTION

Question. Mr. Secretary, given the fact that much needs to be done to protect the working man and woman in this country, can you explain to me why the FY 1990 budget calls for a 35 percent reduction in occupational safety and health?

Answer. The FY 1990 budget requested a reduction in NIOSH based on the philosophy that States and industry should increase support in this area. While I agree with this philosophy, I believe the timing should be delayed and have proposed to OMB that NIOSH remain at the FY 1989 level.

Question. Do you support these proposals in the budget, which was prepared before you became Secretary of Health?

Answer. Having reviewed the Department's original 1990 request, I have indicated to OMB my preference to reallocate some of the Department's 1990 resources to fund several health profession programs. Proposals to eliminate categorical health professions training reflect tight budgetary constraints and a number of competing priorities (AIDS, biomedical research, substance abuse prevention and treatment) and the Federal

government's successful efforts in this area over the last two decades. Through Medicare direct and indirect medical education payments to hospitals, the Health Education and Assistance Loans and the Health Profession and Nursing Student Loan funds, the Department will continue to support health professions training at a level of approximately $2.6 billion.

HEALTH PROFESSIONALS

Question. Do you think the "free market" will take care of distributing health professionals to where they are needed?

Answer. At this time there is an overall surplus of physicians in this country. Over the past few years we have seen some diffusion or voluntary redistribution of health professionals to areas where once there were few or none. This diffusion has occurred most notably in moderate sized rural areas. The very remote rural areas and the most impoverished inner-city jurisdiction have yet to attract significant numbers of health care providers and remain, for the most part, underserved areas.

Question. Are we training enough primary care health professionals to meet current and future need?

Answer. At this time we have both the training capacity and the total aggregate supply of physicians to meet the Nation's needs for the foreseeable future. There still remains some concern about the distribution of this supply among specialists in geographic areas.

Question. Will the market take care of this, or do you think there is a role for the Federal government to play? If so, what is the appropriate Federal role?

Answer. The Federal role in affecting a redistribution of the physician supply is somewhat limited. I have indicated to OMB my intention to maintain some limited role in this area. In general, the Federal government is best suited to helping State health officials and the private medical community to identify possible manpower issues and assist in the development of appropriate responses.

ADMINISTRATIVE COSTS

Question. Federal payments for administrative costs under the AFDC, Medicaid, and Food Stamp programs have increased from $1.4 billion in 1977 to over $3.4 billion in 1987. Are proposals to reduce administrative costs under these programs--either jointly or in combination--still under consideration?

Answer. The Bush Budget includes funding for AFDC State administrative costs in the residual category. The Reagan Budget, which may serve as a useful starting point for negotiations with Congress, proposed eliminating the enhanced matching rates currently available in AFDC for systems development, dedicated fraud detection systems, and alien verification (SAVE). The resulting level for FY 1989 would then be frozen and straightlined into FY 1990.

Question. Please describe recent efforts to reduce these administrative costs in the AFDC program.

Answer. Recent efforts to reduce excessive AFDC administrative costs have focussed on proposed legislation.

During this past year we developed a legislative proposal included in the FY 1990 Reagan Budget to freeze AFDC State and local administrative costs at the FY 1989 level. In subsequent years this cap would increase by the amount of the GNP deflator. Administrative costs related to AFDC work activities would be excluded from the capped amount. In addition, we have proposed in the Reagan Budget to set the Federal match of State and local administrative costs at 50%; eliminating enhanced matching rates for systems development (90%), dedicated fraud detection systems (75%), and the SAVE program (100%). We believe these proposals would promote State and local administrative efficiencies.

We have also developed management initiatives which promote effective use of information systems, technology, enhanced software, skills development and staff training. initiative as

Question. Will you work with Secretary Dole to make sure this program is fully coordinated with existing activities, such as those funded under the JOB Training Partnership Act?

Answer. Yes. At the Federal level the Department is already working closely with the Department of Labor, as well as the Departments of Education and Interior, to assure that the JOBS program is fully coordinated with the services provided under the Job Training Partnership ACT (JTPA), and other employment and education programs. These Departments participated in meetings held by HHS with representatives of State agencies and Indian Tribes on the implementation of the JOBS program. In the development of the proposed JOBS regulations, we sought their advice and input. They have provided significant input and they have helped to identify existing resources to prevent duplication of services and to assure that other program services are available to JOBS participants.

As part of our goal to assure coordination at the Federal level and to promote it at the State and local levels, we are sponsoring a JOBS coordination workshop on May 5 with staff from the Departments of Labor, Education and Interior. We expect to develop strategies to overcome some of the barriers to coordination at the Federal and State levels and to develop plans to better utilize existing services. Over the past few months HHS staff and staff from the Departments of Labor, Education and Interior have participated in a number of joint workshops to promote coordination. These efforts will continue.

At the State level, the JOBS plan must be consistent with JTPA coordination criteria and must be reviewed by the State Job Training Coordinating Council (SJTCC). In our regulations, we are strongly encouraging the State title IV-A agency to meet regularly with the SJTCC regarding the planning and implementation of the JOBS program to identify common JOBS-JTPA activities and services, and to develop an integrated strategy that ensures that eligible

AFDC recipients receive training and employment services in an effective, non-duplicative manner.

Question. What sense does it make to create this new program, for which $350 million is requested in your fiscal 1990 budget, only to cut other Federal job training programs by $850 million?

Answer. The Administration favored enactment of the JOBS program because it targets scarce Federal job training resources to the long-term AFDC recipients and teenage parents to enable them to become self-sufficient and avoid welfare dependence. The FY 1990 budget President Reagan submitted in January requested sufficient funds for all expected costs for employment and job training programs funded through HHS accounts. The new work program account includes funds for JOBS (Title IV-F) and WIN (Title IV-C) work programs. Full funding was proposed for AFDC (Title IV-A) work program expenditures as they were not subject to the Reagan-proposed cap on Federal funding of State administrative expenditures.

Apart from WIN and WIN Demonstrations, which are replaced by JOBS, there are no other categorically targeted work programs for AFDC parents. We believe that questions regarding the rationale for reductions in other training and employment programs run by the Departments of Education and of Labor could be better answered by those Departments.

DEMONSTRATION PROJECTS

Question. The recently enacted welfare reform legislation authorized $4 million for demonstration projects to help non-custodial parent enforce vistation rights with their children. Does the Administration support this program, and if so, why were no funds requested for demonstration grants?

Answer. We agree that absent parents owe children emotional as well as financial support. Generally, States base custody decisions and visitation "rights" on what benefits the children. While we would generally encourage as much visitation as is feasible, we believe the Federal role should be focused on getting financial and medical support for children whose absent parents try not to pay. We believe visitation issues should remain more appropriately within the purview of the States.

The Family Support Act calls for numerous evaluations. Decisions on funding will be made in the context of the outcome of funding under the flexible freeze for all FSA research and demonstration projects.

Question. Wouldn't fathers be more likely to meet their child support obligations if they were able to visit with their children?

Answer. There is only anecdotal evidence about payment habits of absent parents when custodial parents limit visitation. The biggest social problems is absent parents who are not interested in visiting their children, and who try not to pay child support. The Federal government focuses its efforts on the fundamental problem of securing cash and medical support.

Common sense suggests that absent parents who try not to pay probably do not visit, and ones who care enough to visit regularly probably care enough to pay. As a result, it is not surprising that lower payment probabilities have been attributed to declining contact and a weakened father-child relationship. The various studies to date leave the impression that cooperation, contact, and child support payments are very strongly interwoven; however, no empirical data have been found that examine these relationships, or that attempt to unravel their causal connections. Numerous authors argue that low levels of contact are associated with low child support payments by absent parents, however; abandonment rather than denial of access may be the cause. As a result, there is no evidence that spending Federal outlays on visitation issues is a cost-effective way to increase child support payments.

Question. If Congress were to fund this program, what would be the most logical Federal administrative agency? (Outside the Office of Child Support Enforcement, which might have an adversarial relationship.)

Answer. The Office of Child Support Enforcement is the logical choice to administer this project. If a decision is made to place this program under OCSE, I can assure you that staff there will treat the demonstrations with the same professionalism that is afforded other project areas.

Question. Who would be eligible to apply for grants?

Answer. The law states that, "Any State may establish and conduct one or more demonstration projects..." in this area.

REFUGEE ADMISSIONS POLICIES

Question. Why should the State and local governments have to shoulder the burden for Federal refugee admissions policies?

Answer. The FY 1990 Bush Budget includes Refugee Assistance in the "residual" category. The Bush Budget does not propose specific budget authority or outlay amounts for spending which falls into this "residual" category. FY 1990 Refugee Assistance funding will be set through negotiations with Congress. The FY 1990 Reagan Budget may serve as useful starting point for these negotiations.

Given the high Federal budget deficit and the need to encourage States to promote refugee self-sufficiency as quickly as possible, the Department has shortened the period of 100% Federal reimbursement for cash and medical assistance for categorically eligible refugees (those receiving AFDC, Medicaid or SSI) in FY 1990 to 15 months from the 1989 policy of 24 months. After the first 15 months, Federal reimbursement would drop back from 100% to the AFDC matching rate averaging at 55%. This policy change does not preclude assistance to refugees after the initial 15 month period. Refugees will continue to receive public assistance as long as they are eligible.

RELATIVE VALUE SCALE

Question. Do you support enactment of a relative value scale?

Answer. I believe that RVS studies have been extremely useful in focusing attention on payments for physician services. It is very clear to most observers of our present system that we have been driven by procedurally-oriented payment mechanisms and have not given sufficient recognition or weighting to the cognitive-based areas. Pediatrics, for example, happens to be a specialty to which we entrust the future health of our children; and therefore, in terms of productive years of growth, development and optimal development, there is no other specialty that has that kind of responsibility. Yet, overall, pediatricians are among the lowest paid of the various specialists.

The 1990 President's Budget reflects a gradual approach toward payment equity. The Budget proposes a 12 percent reduction in payment levels for certain overpriced procedures. Exclusive of the procedures identified as overpriced, it includes an overall 8 percent reduction in payments for radiology, anesthesiology and surgery services. The RVS studies and other evidence indicate that these services are generally overpriced. For non-primary care services of physicians, the budget proposes no increase in prevailing charges for 1990, and a one percent increase in each of the years 1991 and 1992. For primary care services, the budget proposes to increase prevailing charges by the full Medicare Economic Index (MEI) each year.

I feel that activities such as the relative value scale are performing a good service because the value for the services, as we currently pay for them, is not appropriately balanced. I add one note of caution in terms of adopting an RVS fee schedule for Medicare reimbursements. While an RVS might help to correct some of the perceived inequities on the price side, physician income redistributions could lead to increased volume and higher Medicare expenditures.

Question. Does your Department support payment equity to rural doctors?

Answer. Because most of the services provided in rural areas are primary care services, the President's FY 1990 Budget proposals would generally increase payments to physicians in rural areas. In addition, we are currently funding a major study of differences in costs of practice by the Urban Institute. After that study has been completed, we will have a better understanding of the costs of practice in rural areas.

Additionally, the Department is reviewing the Physician Payment Review Commission's recommendation that expenditure targets accompany any movement toward a relative-value based fee schedule.

RURAL CARE

Question. What actions are you proposing to restore access to care in rural areas? Do you support eliminating the urban rural differential?

Answer. First, we need to do everything we can to remove barriers that discourage medical professionals from practicing in rural areas, particularly differences in Medicare payment rates. We need to address the Medicare payment differences between primary and non-primary care services.

Second, we need to examine the equity of the Medicare payment difference between urban and rural hospitals.

And third, we also need to continue to target personnel available through the National Health Service Corps to rural areas.

Question. Will you be forwarding legislation to Congress to provide a higher update to rural hospitals, exempt them from the additional capital cuts, or to make other adjustments?

Answer. Proposed legislation to implement the Medicare proposals in the 1990 budget was sent to Congress on March 1, 1989. We are currently preparing the proposed regulation containing changes to the Medicare's Prospective Payment System which pays for inpatient hospital services. This regulation is scheduled for publication on or before May 1, 1989

Question. Would you support an access index for hospitals that are necessary to providing access to care? An access index would recognize that these hospitals are vital to maintaining services to remote areas or special populations.

Answer. We are committed to ensuring access to hospitals for all Medicare beneficiaries. Currently, under the Prospective Payment System, certain hospitals can be qualify for sole community status, which affords them special payment protection. A sole community hospital is one that, by reason of factors such as isolated location, weather conditions, travel conditions or absence of other hospital is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries.

GDM APPROPRIATION

Question. While most programs are slated for level funding in FY 1990, you have requested an increase in the GDM appropriation of $16.6 million (28 percent) over FY 1989.

What is the rationale for this extraordinary growth?

Answer. The budget increase for General Departmental Management (GDM) is due principally to two items:

- The continuation of office automation efforts in the Office of the Secretary (OS) and the establishment of connectivity (electronic information exchange) throughout the Department;

- Special Initiative projects which benefit all of the Department's Operating Divisions and which were previously funded by them, but which will now be both managed and funded in OS.

TRANSITION COSTS

Question. What are the Department's transition costs to date, and what are the projected total costs?

Answer. Through March 31, the Department's transition costs totalled $185,000. Total FY 1989 transition costs are expected to come to $344,000.

ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

Question. You have requested an increase in the budget for the Assistant Secretary for Management and Budget from $21 million to almost $27 million.

What is the reason for this 27 percent hike?

Answer. The major reasons for the increase in the budget for the Office of the Assistant Secretary for Management and Budget (ASMB) are the effect of the January 1989 pay raise and the increased funding for OS automation initiatives.

Question. How much of the request is for the Information Resources Management plan?

Answer. Of the total FY 1990 budget estimate of $27 million for ASMB, approximately $12 million will be used for Information Resources Management-related activities (including personnel and other pay-related costs).

ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

Question. What are the total funds available to ASPE from all sources?

Answer. The total amount of FY 1990 funding proposed for the Office of the Assistant Secretary for Planning and Evaluation (ASPE) from all sources is $18.4 million ($5.0 million in Policy Research, $7.2 million in General Departmental Management, and $6.2 million in One Percent Evaluation). This is approximately the same amount as in FY 1989.

However, the FY 1990 request does include two changes from FY 1989: a decrease in Policy Research for the special funding for the Institute for Research on Poverty at the University of Wisconsin, and an increase in the GDM account for office space modification costs and for projects to support the human resources agenda of Congress and the new Administration.

Question. How much is being spent for ASPE's program evaluation?

Answer. We plan to spend $6.2 million for program evaluation under the One Percent Evaluation fund.

Question. How does ASPE coordinate the research conducted by the OPDIVs?

Answer. There are several coordination mechanisms which focus on policy-relevant research and program evaluation. First, each year ASPE provides the Department's Operating Divisions (OPDIV) with guidance for planning research and evaluation activities. These guidelines provide a summary of Secretarial policy priorities, their implications for research and evaluation, and instructions and schedules for submitting annual plans for review.

Research and policy staff in the Office of the Secretary review the plans, in large part to identify opportunities for coordination among the various research offices. This review also identifies important research questions which have not been addressed in agency plans, and instances in which the needs of one agency can be satisfied by small modifications to the plans of another agency. Following the review, opportunities for coordination and improvements in plans are discussed with the OPDIV staffs, and plans are modified. The primary purpose of this process is the sharing of information, rather than the approval or disapproval of projects.

Second, ASPE coordinates the development of specialized research agendas for particular topics of high priority which involve more than one agency or OPDIV. Current examples include research agenda related to adolescent pregnancy, health care capitation, patient outcome improvement, medical liability, catastrophic health care coverage, and the homeless.

Third, ASPE provides for the exchange of research and evaluation plans and project proposals among agencies involved in related areas of research.

Finally, as a service to HHS research and evaluation staff, policy offices, and others both inside and outside the Executive Branch, ASPE operates a Policy Information Center which furnishes information on ongoing and completed research conducted by HHS. This provides ready access to specific studies and to personal contacts in research areas which are being considered.

Because there are well-developed peer review systems at the National Institutes of Health and at the Alcohol, Drug Abuse and Mental Health Administration, the research activities of these organizations are not included in the planning and coordination activities described above.

Question. Does ASPE have authority over what research is conducted by the OPDIVs?

Answer. In general, ASPE's authority is limited to the review of research and evaluation plans and priorities. The purpose of such reviews is to ensure that agencies have adequate plans, that they address major research priorities, and that they take into account all related activities in other research agencies of the Department. In program areas where research may help shape or influence Departmental policies and program administration, ASPE may ask for continued involvement in the design of research projects.

As noted above, ASPE has a more restricted role in biomedical, behavioral and clinical research, focussing on selected questions of research administration and management rather than on what research is conducted.

Question. How does ASPE's Policy Research program compliment and differ from the IG's analyses and inspections?

Answer. The two programs differ in several respects. First, the Inspector General's (IG) program inspections are short-term (usually completed in six months or less), rely primarily on generalist, in-house staff for data collection and analysis, and primarily address specific aspects of how existing programs are administered.

The Policy Research program supports research on more global and fundamental emerging issues of social policy, e.g., welfare dependency, long-term care, and health care cost containment. Its major purpose is to identify and assess new approaches to these continuing issues. The scope is well beyond individual HHS programs. The program relies primarily on the data collection and analysis of researchers outside the Department who have a demonstrated expertise in the field.

Question. What are the specific plans for ASPE's work in FY 1990 to assist the homeless under the McKinney Act?

Answer. ASPE coordinates the Department's implementation of the McKinney homeless assistance programs, and provides staff support to the Secretary in his role as Vice Chairman of the Interagency Council on the Homeless. Specific activities for FY 1990 include:

- o developing a cross-cutting research and evaluation agenda on homeless issues;
- o tracking the progress of HHS programs in addressing homelessness;
- o coordinating preparation of the report to Congress on shelter for homeless AFDC recipients;
- o monitoring the homelessness study being conducted by the Institute for Research on Poverty;
- o coordinating HHS oversight of the joint Robert Wood Johnson/ HHS/HUD demonstration of improved services to the chronically mentally ill, including homeless mentally ill persons; and
- o continuing policy development activities concerning homeless issues.

SPECIAL INITIATIVES

Question. The budget proposes breaking out funding for special initiatives in FY 1990, and requests an increase of $5.7 million for these projects.

Please provide the Subcommittee with a proposed budget for special initiatives.

Answer. The FY 1990 request for Special Initiatives totals $8.3 million. The principal items to be funded from this amount are:

Information Resources Management (IRM)	$5.2 million
Centralized Activities	
Procurement Management Review	$ .8
Connectivity	.4
Southwest Training Center	.3
Executive Management and Development	.3
Media Outreach	.2
Payment Management System (SMARTLINK)	.2
Automated Information Systems Security	.1
Safety and Health Program Evaluation	.1
Safety Management Information System	.1
Other projects/activities	.6
Subtotal, Centralized Activities	$3.1
TOTAL, Special Initiatives	$8.3 million

INFORMATION RESOURCES MANAGEMENT

Question. Funds are requested for Information Resources Management (IRM) in Special Initiatives, in the Working Capital Fund for IRM enhancements, for the Assistant Secretary for Management and Budget to develop the IRM strategic plan and purchase computer workstations, and in other staff divisions.

Who oversees the IRM plan, who is responsible for computer purchases, and what is the total budget for the IRM plan?

Answer. The Office of Information Resources Management, within the Office of the Assistant Secretary for Management and Budget, oversees the IRM plan and maintains the contracts used by the Office of the Secretary (OS). Offices within OS can make IRM-related purchases of up to $5,000 before ASMB approval is required.

Total IRM funds requested for OS for FY 1990, excluding personnel and printing costs, are:

General Departmental Management	
Staff Divisions	$10.8 million
Special Initiatives	5.2
Office of the General Counsel	2.0
Office for Civil Rights	1.1
Office of the Inspector General	5.4
Policy Research	.9
TOTAL, IRM	$25.4 million

WORKING CAPITAL FUND

Question. The budget proposes increasing the Working Capital Fund by $5.4 million from FY 1989 to FY 1990.

How would the increase be used?

Answer. The increase from FY 1989 to FY 1990 is comprised of increases in several of the Working Capital Fund activities, as detailed below:

FY 1989 Estimated Obligations	$72.8 million
Payroll	$ 2.5
Accounting Systems	.9
IRM Enhancements	1.8
Multi-Regional Bargaining Agreement	.2
TOTAL Increases	$ 5.4
FY 1990 Congressional Request	$78.2 million

Payroll. During FY 1990, new automated payroll subsystems for retirement, unemployment compensation, health benefits, time and attendance, and savings bonds are scheduled to be implemented. The increased funding will cover the costs of coding, testing and implementing these subsystems, and the resulting increase in ADP processing time. Also included is the cost of contract support for additional payroll clerks which will be necessary to provide adequate service levels.

Accounting Systems. This increase will fund the replacement of the current Office of the Secretary (OS)/Office of Human Development Services' Accounting System with more efficient, "off-the-shelf" software. In addition, funds are included for converting data from the old system, modifying and enhancing the new software to meet specific HHS requirements, and implementing additional software modules to support the travel management and procurement functions.

IRM Enhancements. These funds will be used to move the Department closer to its goal of an OS-wide network of multi-functional, personal computer-based workstations. These workstations and communications networks will be used for general purpose office automation, end-user computing, and existing OS systems.

Multi-Regional Bargaining Agreement. These funds will support activities related to the collective bargaining agreement between the Department's ten Regional Offices and the National Treasury Employees Union. This activity was previously funded on a reimbursable basis under the General Departmental Management appropriation. Funding will cover travel costs for union representatives, management officials and witnesses to bargaining sessions, arbitration proceedings, grievance meetings, and Unfair Labor Practice hearings. Also included are funds to begin preparations for bargaining a new agreement (the current agreement expires in FY 1991).

Question. The Working Capital Fund Charter requires an annual audit of its operations.

When was the last audit conducted, and what are the results of the audit?

Answer. The first audit of the enhanced Working Capital Fund (WCF) is an audit of the FY 1988 WCF financial statements. This

audit has not yet been completed, but the expected completion date is April 30, 1989. Because of the drastic change in the composition of the Fund in FY 1988 and a lack of previous year audited financial statements to use as a starting point, the audit has taken longer than anticipated to complete. However, in subsequent years the annual audit is expected to be completed at an earlier date.

Upon completion of the FY 1988 audit, the WCF Financial Manager will ensure that each of the Fund's Activity Managers addresses all pertinent items within their activity areas. After approval by the WCF Board of Governors, appropriate responses to all audit findings and recommendations will be implemented as soon as practicable, subject to resource limitations and funding constraints.

Question. The Committee authorized a major enhancement of the Working Capital Fund two years ago.

What is the Department's experience with the enhanced fund? How has it improved financial management?

Answer. After a period of initial adjustment, the enhanced Working Capital Fund is working well and accomplishing its purpose. The WCF Charter and the WCF Board of Governors have provided structure, direction and oversight for the Fund. The Board's current priority is to ensure that the Fund's major activities operate in the most competitive, business-like manner possible by reducing operating costs and by basing the price of their services on true cost to the customer ("fee-for-service"), rather than on an allocation formula.

The current structure of the WCF is designed to ensure maximum fiscal accountability and efficiency of service. In addition, the financial operations of the Fund are managed by a professional Financial Manager, who is responsible for all fiscal and budgetary policies and procedures. The Financial Manager reports to the WCF Board and provides the daily "hands on" management needed to identify potential problem areas and ensure that they are quickly resolved. The WCF Charter, the management of the Fund by its Board of Governors, the capital budget process, and the annual audit of the Fund by an independent source are indicative of the management systems and controls which now place this WCF at the forefront of Federal revolving funds.

Question. The Office of the Secretary bills the Department's Operating Divisions for activities in the Working Capital Fund (WCF).

How much for the bill for the WCF do the Operating Divisions pay?

Answer. The approximate percentage which each Operating Division (OPDIV) will pay of the total $78.2 million WCF estimate for FY 1990 is as follows:

Public Health Service	25.2%
Social Security Administration	46.7%
Health Care Financing Administration	7.7%
Human Development Services	6.5%
Family Support Administration	4.1%
Office of the Secretary	9.8%
TOTAL	100.0%

These percentages are based on the latest estimates of OPDIV activity levels for both allocable and fee-for-service activities. The actual percentages charged to the OPDIVs may be different, as several WCF activities will be converted from an allocated to a fee-for-service billing basis in FY 1990. Under fee-for-service, billings will be calculated on a cost per unit basis, with the unit cost based upon the actual cost of performing a specific service. Therefore, although unit costs will normally remain constant throughout a fiscal year, the total charge to an OPDIV may vary from the budgeted amount if the volume of fee-for-service activity actually used by the OPDIV varies from the initial estimate.

WORKFORCE EFFECTIVENESS

Question. The cost of the federal workforce is enormous -- an estimated $119 billion a year for salaries and benefits. With the third largest non-military workforce in the federal government, HHS's share of this investment is substantial. HHS staff administers programs that cost $1 billion a day.

Given the enormity of the HHS budget and the high cost for personnel, what steps has the Office of the Secretary taken to establish human resource planning processes throughout the Department to ensure an effective workforce?

Answer. The Department of Health and Human Services does have both a large work force and a large payroll. However, its workforce is shrinking at a time when it is experiencing significant growth in both program and service responsibilities to the public.

During the past ten years, HHS has reduced its workforce by 40,000 employees, or almost 25 percent. While some of this has been due to the transfer of functions such as public health hospitals out of the Federal government, the population which HHS serves and the services which it provides to that population have continued to increase. To compensate, the Department has made significant productivity improvements and has been able to provide more services to more people and institutions than ever before in its history, with its smallest work force in more than 15 years.

The Department currently has a workforce encompassing several hundred occupational specialties and consisting of approximately two-thirds women. Also, one-third of the total number of employees are minorities. While the HHS workforce has historically been determined by demand, i.e., the nature of the jobs and the focus of HHS programs has been selectively attractive to women and minorities, we will soon have a work force determined by supply. In just 12 years, 85 percent of all new entrants into the national labor force will be women, minorities, or immigrants.

HHS components which have fewer women and minorities will find themselves moving rapidly toward the Departmental norms, while those components already at the norms will most likely find themselves with an even greater representation among these groups. In addition, the median age of the HHS workforce is already five years greater than the national labor force age. In essence, HHS has today the workforce of the future.

Several issues clearly point to the need for a more active, "corporate" role for the Office of the Secretary (OS) in promoting workforce planning. These unclude: an aging workforce; increased labor force representation among women and minorities; the need to strike a balance between women, work, and families; and the need for a better educated and skilled workforce to keep our programs viable. In response to these and other events, OS has taken the following positive steps.

First, OS has taken a strong and active role in planning for executive resources. OS is active in not only the recruitment, selection, and management of current executive resources, but also in planning for future executive resources through the development of a succession planning model for use in HHS. This model covers more than 600 positions which provide the Department's political and career leadership.

Second, OS has established a Center for Management Excellence in the Office of the Assistant Secretary for Personnel Administration (ASPER). As part of its mission, this Center is responsible for conducting workforce studies and analyses which can be used to identify workforce planning issues.

Third, through the efforts of ASPER and the Assistant Secretary for Management and Budget, OS developed a workforce planning briefing which was given to each Operating Division last summer. This briefing focused on some of the major workforce trends and issues facing HHS and on possible management responses to these issues.

Finally, last October OS sponsored the Department's First Annual Conference on Quality and Productivity. This conference was very successful in bringing quality and productivity issues to the attention of the Department's managers. OS plans to conduct another quality conference this fall.

The Department recognizes the need for workforce planning in ensuring an effective workforce. While OS is prepared to work towards the goal of establishing a successful workforce planning process, we have not yet determined what type of planning process would be most effective in HHS, or which mechanisms should be included. In addition, we have not yet determined a workable method for integrating workforce planning and budget planning, a problem which many agencies face. However, we are confident that the Department will be able to establish a workable process that will ensure an effective HHS workforce, both for today and for the future.

OFFICE OF THE GENERAL COUNSEL

Question. Your budget proposes consolidating the operations of the Office of the General Counsel into one account. In the past, funds for OGC have come from three sources — the Working Capital Fund, transfers from the Social Security Administration, and from the General Departmental Management account.

Have there been any negative effects of having three separate sources of funding to date?

Answer. There have been substantial negative effects.

First, because of the existence of three separate personnel ceilings, the Office of the General Counsel (OGC) has lost its flexibility to assign cases and workloads to personnel according to who is in the best position to effectively handle the work.

In addition, management of three separate budgets and personnel ceilings is inherently complicated and has substantially increased the amount of time needed for the administration and management of OGC. It has also required the creation of arbitrary distinctions between "accounts" which do not serve any purpose other than to confuse and distort the management of OGC.

The requirements imposed on personnel funded under the Inter-Office Transfer Voucher (IOTV), i.e., that they must engage only in Social Security disability litigation, have created a situation in which it is difficult to hire and retain competent staff. Moreover, it is extraordinarily inefficient, since it precludes disability litigation staff from carrying out other very similar activities which they would be able to handle most effectively. For example, such staff could not render legal opinions on the issue of disability determinations, or on litigation dealing with individual eligibility for disability benefits on factors other than disability itself, such as whether an individual is the legal spouse of the disability beneficiary.

The concept of the Working Capital Fund, i.e., that each agency client contributes a certain percentage of the cost and then is entitled to only a certain level of effort, does not easily translate to the provision of legal services, since the largest portion of OGC's resources is engaged in defensive litigation, which cannot be internally controlled.

Question. With a consolidated OGC account, will overhead costs be lower?

Answer. Consolidation will not reduce our overhead costs per se. However, we will clearly be able to save the time currently being spent by our administrative staff in Headquarters and in our ten regional offices in trying to manage three separate budgets and FTE ceilings; we will then be able to devote this time to other needed tasks.

Question. What about your operations would you do differently under the consolidation?

Answer. With a consolidated OGC account we would have the flexibility to constantly assess, as vacancies occur, how to best deploy our resources to meet changing needs. Moreover, in dealing with existing staff — particularly the staff covered by the IOTV and under the Working Capital Fund — we would assign work based upon ability to do it effectively and efficiently, rather than because of particular funding restraints.

Question. Would the consolidation absorb the proposed cut of 15 OGC FTEs?

Answer. We anticipate being able to absorb the proposed cut of 15 FTEs primarily from a reduction in the level of support services that will be needed when our office automation effort is completed. However, the consolidated budget will also help us to better manage our resources by giving us the flexibility to assign support staff based on workload. Finally, the reduction in the amount of time necessary to manage the OGC budget will also be a significant factor in our ability to absorb the FTE cut without sacrificing the quality of our services.

Question. Would the consolidation improve your ability to assign lawyers to meet special needs or contingencies?

Answer. Yes, most definitely. The artificial requirements resulting from the current arrangement, i.e., that personnel funded from a specific budget must engage only in the work assigned to that particular ceiling, would be eliminated. With the consolidation, OGC would be able to reassign its staff to meet the unique and ever-changing legal needs of the Department. For example, we would be able to shift resources in the field from handling the work of one Operating Division to handling the work of another, if there were a special initiative requiring increased and unexpected lawyer resources. A good example of this is the recent increased activity by HCFA in reviewing nursing homes for compliance with the participation requirement.

Question. Why aren't the 23 FTEs for OCR included in the consolidated OGC request?

Answer. Both FTEs and funding for the Civil Rights attorneys have been carried in the Office for Civil Rights budget since approximately 1970. The original purpose of this arrangement was to have all Office of the Secretary resources for civil rights enforcement be located together, so as to allow an overall evaluation of the resources being devoted to this activity. This arrangement, which covers only 23 FTEs nationwide, has not been the source of any significant problems.

OFFICE FOR CIVIL RIGHTS

Question. The FY 1990 budget, for the first time in a decade, does not propose a reduction in OCR staffing levels.

Does this represent a change on civil rights policies in the Department?

Answer. No, the FY 1990 budget request does not represent a policy change. OCR is requesting 325 FTE, the same staffing level

as in FY 1989, to handle the complaint workload and to carry out other civil rights compliance activities.

Question. In last year's justification, you forecasted receiving 1,166 new complaints in FY 1988. The actual number of complaints received, according to this year's justification, was 1,589, an increase of 36 percent over the estimate.

What accounts for this increase? Have you changed your method of estimating new complaints?

Answer. The number of complaints received increased in FY 1988 primarily because of a sharp rise in both AIDS-related complaints and in complaints of improper patient transfers ("patient dumping"). OCR has not changed its method of estimating complaint receipts. Estimates of FY 1989 and FY 1990 receipts contained in the budget justification are based on past experience and other pertinent criteria.

Question. OCR closed 435 more discrimination complaints in FY 1988 (1,529) than in FY 1987 (1,094), a 40 percent increase.

Please provide the Subcommittee with a report on enforcement activities under Section 504, detailing actions taken in FY 1989 and prospective actions for FY 1990.

Answer. Of the 1,529 complaints closed during FY 1988, 726 (47 percent) involved Section 504 issues. These included 134 AIDS complaint closures. Through March 31, 1989, 320 of 702 FY 1989 complaint closures (46 percent) involved Section 504 issues, including 86 AIDS complaint closures. Based on recent trends, we anticipate that 45 to 50 percent of our complaint closures in FY 1990 will involve Section 504 issues.

Question. How do you account for the difference — did the types of cases change from one year to the next?

Answer. The increase in complaint closures between FY 1987 and FY 1988 may be attributed to OCR productivity improvements, to reallocation of staff from other compliance activities, and to management's setting as priorities the closure of older complaints and the expedited handling of AIDS complaints.

During FY 1988, the total increase in the number of complaints <u>received</u> included 128 for AIDS complaints and 152 for patient dumping complaints. As a result, more than half of the total FY 1988 increase in complaint <u>closures</u> also came from these two workloads (114 for AIDS and 122 for patient dumping).

Question. What was the average staff time spent on each case in FY 1987 and FY 1988?

Answer. On average, 163 days elapsed between the intake and closure of complaints in FY 1987, and 160 days in FY 1988.

POLICY RESEARCH

Question. The percentage of Americans living below the poverty line did not decrease during the Reagan Administration, but President Bush has called for a kinder and gentler nation.

How would the proposed FY 1990 budget bring about a kinder and gentler nation, and how will Policy research contribute?

Answer. With respect to the Department as a whole, the FY 1990 budget contributes in a number of major ways, including funding for implementing welfare reforms in the Family Support Act, for health care for the poor, for a special initiative to enhance access to health care for pregnant women and children, for the McKinney Act for the homeless, for Social Security benefits for the elderly and disabled, and for many other similar activities.

Concerning the Policy Research budget in particular, almost all of our research addresses which issues concern families and the disadvantaged — clearly key groups in a "kinder and gentler America." More specifically, there are four basic priorities that directly address thir goal.

The first is to find better ways to assist the poor, particularly to help reduce and prevent welfare dependency. Studies in this area will focus on evaluation of the employment component of the recently enacted Family Support Act, on child support and paternity, on the role of support services in reducing dependency, and on dependency problems of special populations.

Second, we are examining long-term care issues which affect the disabled and impaired elderly. We have planned research which will continue to collect information and develop data bases, so that we can model and assess the costs and impact of various policy proposals. We will also undertake research to identify the extent to which long-term care expenses are a catastrophic burden. Finally, we will continue research into the quality and cost of post-acute care, and plan to find more out about the disabled, particularly the services they use and the gaps and overlaps in those services.

Third, in the health policy area, a major priority is studies on health care for the poor. Specifically, we will continue to assemble data bases to assess the impact of proposals for improving access to such care. We will also examine how to continue to improve care for pregnant women and young children.

Our fourth priority is research on the family. In addition to the welfare dependency studies already mentioned, we will examine child care issues and issues concerning families with special problems, such as teen-aged parents, pediatric AIDS, and homeless families.

Question. What initiatives does the Department have to reduce the incidence of poverty?

Answer. The major initiative of the Department in this area is implementation of the Family Support Act of 1988. The Act's

JOBS program is designed to encourage welfare recipients to obtain employment. Other provisions of the Act will support the recipients' early experiences in the labor market through extended Medicaid and child care transition benefits, and should lead to self-sufficiency without government support.

The Department will also be providing benefits under the Medicare Catastrophic Coverage Act of 1988. High medical expenses can sometime drive the elderly into poverty, even if they have enough income to live comfortably otherwise. Providing insurance against a catastrophic health event may well prevent such poverty.

The Administration also has several new initiatives designed to reduce poverty. One is the President's child care initiative, designed to support families with either one and two wage earners. This initiative also includes an expansion of the Head Start program. In addition, the Administration is proposing an expansion of Medicaid to cover more pregnant women and infants.

Finally, we are continuing our research program into the causes, correlates, and consequences of poverty. Our major focus in FY 1989 and FY 1990 is on the underclass, but we also plan additional studies of child support payment and paternity establishment.

Question. How much does the Department spend in intramural and extramural research?

Answer. In FY 1989, the Department will spend approximately $7.7 billion in intramural and extramural research — mostly biomedical. Approximately $6.6 billion will be spent for extramural research and $1.1 billion for intramural research.

The proposed budget for FY 1990 includes approximately $8.1 billion for intramural and extramural research — a six percent increase over FY 1989. This includes approximately $7 billion for extramural research and $1.1 billion for intramural research.

Biomedical, behavioral and clinical research of the National Institutes of Health and the Alcohol, Drug Abuse and Mental Health Administration constitute about 95 percent of the Department's intramural and extramural research.

Question. How are the research programs coordinated, and how do you ensure that research is not duplicative and wasteful?

Answer. There are several mechanisms for ensuring coordination of research and for avoiding duplication and waste. First, the Office of the Assistant Secretary for Planning and Evaluation establishes an annual review of research and evaluation activities. This review focuses on opportunities for coordination, on possible gaps in important research, on methodological appropriateness, and on the avoidance of duplication. The results of the review are used in modifying plans and projects.

Second, the Secretary frequently establishes Departmental efforts or working groups to develop specialized research agenda for topics which involve multiple agencies. The development of

such specialized agendas helps to ensure that relevant offices work together in the definition of important research, and that quality research results. Research on pediatric AIDS is an example of this type of coordination.

Third, the Department's Policy Information Center provides information on ongoing and completed research. This provides HHS staff with ready access to specific studies and to staff contacts in research areas which they are considering addressing.

Fourth, each agency has its own project review process to solicit the views of methodological and subject matter experts. Such experts include knowledgeable staff from other offices with experience in or responsibility for the research questions being addressed.

Finally, as a general matter, plans and project proposals are shared broadly across the Department to ensure that research staff are aware of and can participate in or utilize projects that touch on their areas of responsibility.

QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

HEALTH OBJECTIVES

Question. Secretary Sullivan, you stated in your testimony that "we must emphasize health promotion and preventive medicine strategies." Much time and effort has been devoted to developing the health objectives for the nation. Do you think the increase of $50,000 to the Office of Disease Prevention and Health Promotion is adequate to implement the strategies for accomplishing those objectives?

Answer. The $4.5 million budget request for the OASH Office of Disease Prevention and Health Promotion, for which an increase of $50 thousand is proposed for 1990, is a very small component of the more than $5.2 billion which we expect to be spent on prevention-related programs throughout the Department in 1990. This is an increase of about $317 million over the 1989 level.

The role of the Office of Disease Prevention and Health Promotion is primarily one of coordination and leadership for the Department on all prevention-related issues. The $5.2 billion estimate for total prevention spending includes activities such as $1.8 billion in prevention research at NIH and ADAMHA; $574 million for all of CDC's prevention programs; $513 million for FDA's consumer protection functions; $586 million in maternal and child health and infant mortality reduction spending in HRSA; $467 million for AIDS prevention and education activities; $414 million in HCFA reimbursements for Medicaid family planning and infant and child health services, and Medicare pneumococcal pneumonia and hepatitis B vaccinations for adults; $608 million for OHDS support of nutritional meals and other services for the elderly and Headstart children; and $262 million in other prevention efforts in OASH, IHS, and FSA, which includes the $4.5 million for the Office of Disease Prevention and Health

Promotion. All of these activities will contribute to implementing the strategies needed to address the health objectives for the Nation.

Question. Given the wide array of problems affecting rural areas, I would like to know whether you are considering changing or expanding the mission of the Office of Rural Health?

Answer. Access to health care is an issue of some importance to me, both in rural areas and in inner city areas. While I do not envision a realignment of the Office of Rural Health at this juncture, should it become apparent that placing the office in a different organizational context would be beneficial, I would not hesitate to do so.

HEALTH CARE PROFESSIONAL SHORTAGES

Question. Since we have what appears to be a severe shortage of certain health care professionals, such as nurses and allied health personnel, why should we reduce funding for health professions training? If anything, it would seem that we should be considering increases.

Answer. There appears to be several specific health manpower issues which warrant a second look. In reviewing the 1990 request, we have attempted to make some adjustments which will address some of the issues you raise. I have sent forward a budget amendment proposal to OMB which will reallocate some funds for health professions training.

Question. What specific actions will the Department be taking to address the nursing shortage—in other words, what have you done or are planning to do to implement the findings of this report?

Answer. As you know the Commission on Nursing placed much of the onus of addressing the nursing shortage on the private sector medical institutions and on the nursing profession itself. Nonetheless, there are opportunities for us to provide guidance and support to the efforts of the medical community. This we will continue to do through the National Center for Nursing Research, The Division of Nursing in the Health Resources and Services Administration, and the Nursing Student Loan program.

Question. What do you think we can do to attract more nurses to rural areas, and do you know of examples of successful efforts to recruit and retain nurses in rural health care facilities?

Answer. The Nursing Commission made a number of recommendations which would make the nursing career more attractive, including increasing potential compensation, removing the stigma of second class citizenry from the nursing profession, and providing nurses with the maximum range of professional responsibilities. In rural areas in particular, nurses are called upon to provide wide-array of medical services. For some nurses, the wide range of duties and responsibilities of nursing represent a challenge that serves as a positive incentive, if compensation is adequate.

Question. First, how many requests for help have you received from communities needing physicians?

Answer. HRSA has received approximately 2,300 requests from sites indicating a need for physicians.

Question. Second, how many of those communities actually qualify as health manpower shortage areas under your criteria?

Answer. Of the 2,300 sites applying for assistance, approximately 2,100 are designated as health manpower shortage areas (HMSAs).

Question. Third, how many physicians have inquired or applied for the loan repayment program?

Answer. In 1988, 125 physicians applied for participation in the Federal Loan Repayment program of which HRSA matched and supported 20.

Question. Finally, how many of those physicians are you supporting.

Answer. To date, in 1989, 93 physicians and 19 nurses have applied to participate in the Federal Loan Repayment program. HRSA expects to receive several more applications before July after which the majority of awards will be made.

Question. With that as an objective, I would like to know whether you intend to only focus on medical procedures conducted by physicians?

Answer. I view the Medical Effectiveness Initiative as a long-term project that will evolve over time. It has three major components: research; data development and analysis; and information dissemination. It is not conceived, at this time, to be limited to only practices performed by physicians.

Question. Is the focus strictly on physician practices? Couldn't there be some alternative procedures available through other health care providers that would also be cost-effective?

Answer. As you know, the Medical Effectiveness Initiative will look at current practices, of all types, for the same problem, with an eye on identifying differences in patient outcomes. The basic idea is to identify those practices which promote the optimal patient outcome, regardless of the source of the treatment or therapy.

PAYMENT OF NURSES

Question. Nurses, especially highly specialized nurses, perform many of the services for which physicians are being reimbursed, for example, physical exams. Many studies have documented that utilizing nurses to provide these services is a very cost-effective way to deliver health care. What is the department's position on fuller utilization of highly specialized nurses to increase access to health care and on reimbursing them for providing these health care services?

Answer. We support the increasing role that nurses perform in providing medical services; however, our position is that nurses should not be reimbursed directly by Medicare. They are employed by physicians, hospitals, and other providers of medical care, and should be paid by them appropriately for the services that they perform.

Question. I understand that a small staff of the Secretary's Commission on Nursing has been extended to promote ownership of recommendations put forth in the Commission's report. Have you been briefed by the staff on the private sector response to the Report?

Answer. Not yet, although I expect to meet with Dr. Davis, who chaired the Commission, in the future to discuss this.

Question. There had been criticism of DHHS for reluctance to acknowledge the nursing shortage because of the large number of nurses. The Commission's work was well received and viewed as having the Secretary's imprimatur. Department data bases have been less than adequate to understand the scope of a demand-driven shortage. The Bureau of Labor Statistics embodies a substantial database which could compliment DHHS data. Do you anticipate closer collaboration in working together to understand manpower predictions?

Answer. The Bureau of Health Professions within the Health Resources and Services Administration has primary responsibility for tracking the supply and demand of nurses. In its work the Nursing Commission worked closely with and received much assistance from the Bureau. Nonetheless, given the importance of this and other health manpower issues, the Bureau will continue to seek additional data to complement the resources already at hand and to improve our ability to assess nursing supply and demand trends.

LONG TERM CARE

Question. The population of the United States is becoming an increasingly older one with increasing long term care needs. What strategies do you recommend for dealing with this need?

Answer. Currently, the Medicaid program provides chronic, long-term care in nursing facilities to persons who are eligible for Medicaid, primarily through SSI or a State's medically needy program. States also have the option of providing services to persons in home or community based settings. OBRA 1987 contained numerous nursing home reform provisions which will substantially improve the quality of life for Medicaid recipients in nursing homes. We are working to implement these provisions as well as the spousal impoverishment provisions of the Catastrophic legislation. We will need time to carefully evaluate the impact of these legislative changes.

Additionally, I intend to work with senior staff in the Department to study the development of the long term care insurance market and its prospects for providing financial protection to the elderly from the costs of long term care.

NATIONAL HEALTH INSURANCE

Question. The issue of some type of comprehensive national health insurance has been discussed in this country for some time now. What is your position on this issue?

Answer. We are very concerned that all people have access to appropriate health services. To that end, President Bush has proposed expanding the Medicaid program. However, we do not feel that a comprehensive national health insurance approach is best. We believe that a pluralistic approach, with participation by the Federal government, through Medicare and Medicaid, State governments, and the private sector, is a better approach.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

INDIAN HEALTH SERVICE

Question. During the recent hearings before the Subcommittee on Interior and Related Agencies of the Committee on Appropriations, the Indian Health Service (IHS) was asked to provide the level of funding that was necessary to permit IHS to maintain the same level of services in fiscal year 1989 as was provided in fiscal year 1988. The response from the Indian Health Service indicated a need for over $45 million to maintain the fiscal year 1988 level of services in fiscal year 1989. Since IHS is already experiencing a shortfall of funds for this fiscal year, why is the Department of Health and Human Services seeking Congressional approval of a recision request of approximately $12 million in appropriations that have been allocated to the Indian Health Service?

Answer. This recommended reduction of $11.7 million in fiscal year 1989 is part of a government-wide across-the-board offsetting budget amendment, decreasing spending by 1.099 percent, in order to meet critical needs in such areas as veterans affairs and refugee assistance. The Indian Health Service would achieve these savings by delaying construction expenditures. In this way, the most important and first concern of the Service, provision of quality health care services, would not be affected by the proposal.

Question. On October 5, 1988, Public Law 100-472, the Indian Self-Determination Amendments of 1988, was enacted into law, and on November 23, 1988 Public Law 100-713, the Indian Health Care Amendments of 1988, was enacted into law. Recognizing that because of the timing, the provisions contained in these Acts that should have influenced the budget request may not have been considered in the formulation of the fiscal year 1990 budget. Given that the formulation of the fiscal year 1991 budget will begin soon, the Committee would like to know what plans the Department has to request the resources required to fully implement the provisions contained in the two Acts.

Answer. My first opportunity to conduct a full scale review of the program and budgetary needs for all activities in the Department of Health and Human Services will be in the context of preparing the fiscal year 1991 budget. As part of that review, we would certainly expect to consider the impact of recently passed

legislation, such as the Indian Self-Determination Amendments and the Indian Health Care Amendments.

Question. Each year, the Committee directs the Indian Health Service to provide reports to the House and Senate Appropriations Committees, detailing the actual increase in program operation costs due to inflation. The Committee is concerned that because of the rapid rate of inflation associated with health care that the actual purchasing power of the IHS budget request is decreasing at an extremely rapid rate. Is the Secretary aware that the Office of Management and Budget allowances for inflation for the Indian Health Service are understated and will result in further restrictions on the Department's ability to provide health care services to the Indian patient population?

Answer. Spending for health care, and the rate of increase, has a significant impact throughout the Federal budget. As a nation, spending on health care has increased rapidly, more than twice the rate of inflation. The Federal government is the largest payor of health care costs, over 40 percent, and as administrators of these programs we have a responsibility to be prudent purchasers of care. For the Indian Health Service, we must assure that funds are sufficient to maintain the full array of services available to American Indians and Native Americans. In the coming months we will be reviewing the future budgetary needs of the Indian Health Service and we will be mindful of the Federal commitment to the Indian patient population.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

FY 1990 MEDICARE PROPOSALS

Question. Dr. Sullivan, I understand the FY 90 Medicare proposals were part of President Reagan's original budget request to Congress. Is that correct? And these proposals are still part of President Bush's FY 90 proposal?

Answer. We are not necessarily wedded to the specific proposals contained in the budget and would be willing to consider others that would achieve the objective of slowing the growth of Medicare expenditures. We are willing to discuss other approaches with the Congress. But, we cannot let the Medicare program continue to grow at a 14 percent annual growth rate. To do so threatens the financial viability of other needed initiatives as well as the tolerance of the taxpayers to continue to support these important programs.

HOSPITAL PROFIT MARGIN

Question. What is the justification for the proposed cuts and savings? I have been told that the Health Care Financing Administration (HCFA) data show a profit margin for hospitals of less than one percent. What indication do you have that hospitals will be able to sustain the proposed cuts without cutting back on services or closing down altogether?

Answer. We believe that there are still efficiencies that can be achieved in the system. Overall margins for the last year for which we have complete data were 5.3 percent (FY 1987). However certain classes of hospitals have fared very well under PPS and there still remain subsidies in the hospital system that are clearly excessive. We believe that our savings proposals will correct these problems in Medicare payments to hospitals.

OFFICE OF INSPECTOR GENERAL

STATEMENT OF RICHARD KUSSEROW, INSPECTOR GENERAL

PREPARED STATEMENT

Senator HARKIN. Our next witness is Mr. Richard Kusserow, inspector general of Health and Human Services.

As chairman of this subcommittee, I am particularly interested in the inspector general's work. Through careful auditing of expenditures and evaluation of the effectiveness of programs, the inspector general has identified areas of significant potential savings.

I am committed to finding every bit of savings where there are wasteful Federal practices. I appreciate working with the inspector general and his staff. Again, I want to thank you for being so forthcoming and so agreeable to work with on my level and also on the staff level.

So welcome back to the subcommittee, Mr. Kusserow. If you could just summarize your remarks. We certainly appreciate your record. Your statement will be made a part of the record in its entirety.

[The statement follows:]

STATEMENT OF RICHARD P. KUSSEROW

Mr. Chairman,

We are pleased to appear today to present the FY 1990 appropriations request for the Office of Inspector General. The OIG is proud of its mission to protect the integrity of the Department's programs, and those beneficiaries whose health and welfare depends upon them. The resources requested in 1990 reflect our commitment, as do our accomplishments over the past years which you know so well.

During FY 1988, $5.56 billion in settlements, fines, restitutions, receivables and savings resulted from OIG activities and implementation of OIG recommendations. Last year, each dollar invested in the OIG budget returned $74 to the Federal coffers. In addition, recommendations both already made during FYs 1988 and 1989 and those still pending could lead to billions more in savings and dollar recoveries.

In addition, our investigative staffs' efforts resulted in a record 1225 criminal convictions, a seven-fold increase over the last seven years, plus another 466 civil and administrative sanctions of entities and individuals who defrauded or abused our programs or their beneficiaries.

Our budget request includes resources for 1,373 FTE in FY 1990, an increase of 15 FTE from the revised 1989 level. For FY 1990, I am requesting $92,798,000 in obligational authority, of which $49,498,000 would be from FY 1990 appropriations. Additionally, $40,000,000 would be transferred from the Social Security and Medicare trust funds and $3,300,000 million would be transferred from the Catastrophic trust fund for work in support of those programs. This year's request is a modest increase of 4.3 percent, or $3,900,000 from a comparable 1989 level. Over half of that increase will be consumed by inflation, annualization of pay raises, and fixed cost expenses, such as RENT and utilities.

Our budget request only partially compensates for additional workloads arising from new responsibilities legislated by the last Congress, such as the Family Support Act of 1988, which have greatly expanded both the Federal Government's and the Department's programs and enforcement and sanction authorities. However,the resources requested will enable the Office of Inspector General to carry out those new and complex responsibilities.

In 1990, OIG will promulgate new, or have in place existing, regulations designed to implement 60 administrative authorities, which include civil monetary penalty (CMP) authorities and sanction authorities which were enacted over the last 4 years. Seventeen of these new CMP and sanction provisions resulted from the Omnibus Budget Reconciliation Act of 1987 and 14 from the Medicare Catastrophic Coverage Act of 1988. The latter legislation increased OIG's legal and programmatic responsibilities dramatically, and added workloads which simply cannot be absorbed by current staffing. Our 1990 request reflects the additional funding necessary in order to carry out the statutory requirements placed upon HHS by Congress.

The OIG continues to place heavy emphasis on the trust fund programs of Social Security and Medicare, which account for almost 82 percent of the Department's 1990 budget. The magnitude alone of these programs makes them vulnerable to fraud, waste and abuse. In 1990, the OIG program includes a third annual audit of SSA's financial statements, and a review of the implementation of SSA's redesigned debt management system to determine if it will resolve previously established deficiencies affecting SSA's ability to identify, control and collect overpayments to beneficiaries. And, based upon a cycle of studies to monitor client satisfaction with services provided by the Social Security Administration, the OIG is also conducting a Medicare beneficiary satisfaction survey. We also plan to evaluate HCFA's new survey system pertaining to the quality of care provided to Medicaid recipients in federally-certified nursing homes. The new survey system is intended to focus

more directly on deficiencies in care which significantly affect the health, safety and well-being of residents.

As promised before this Committee last year, the OIG established a new audit division for increased oversight of the Public Health Service (PHS) programs. In support of the proposed FY 1990 $1.6 billion PHS funding level for AIDS related activities and in light of recent allegations of research fraud, OIG is currently undertaking a major study to look at policies and procedures used to prevent and deal with scientific misconduct. The OIG will also determine if the review of grant applications at PHS is being conducted thoroughly and in a timely manner without compromising the quality of the grant approval process.

On a similar note, we are increasing audit oversight of the nearly 2,800 colleges and universities for which we have cognizance. This means that for 99 percent of the universities receiving Federal research funding, OIG is the sole Federal agency responsible for conducting audits to determine whether the institution is in compliance with Federal rules. The enormity of the audit universe has meant we have fallen further and further behind in servicing our obligations in these areas. We plan to increase the level of audit activity among universities to stem this trend.

As mentioned earlier, the OIG request reflects a $3,300,000 transfer from the Catastrophic Trust Fund for oversight activities associated with the 1988 law which significantly expanded the Medicare program. Due to the new drug benefit program, our planned projects include the use of the Catastrophic funding for the conduct of surveys and studies on drug utilization, following the period of time from prescription and dispensing to utilization. We will assess whether physicians in certain locations tend to prescribe certain medications. Also, we will assess the extent and causes of noncompliance with medication regimens by the elderly.

Additionally, under the authority of the Catastrophic law, OIG will promulgate regulations implementing sanction provisions relating to the misuse of departmental symbols and emblems which might be used to inappropriately convey Federal support of private sector programs.

In order to implement the increased inspection and investigative activities associated with the Family Support Act of 1988 (Public Law 100-485), additional staff and supporting funding are needed. The employment increase in 1990 will enable us to forge ahead on a number of studies monitoring implementation and effectiveness of the new welfare reform provisions, including an evaluation of paternity establishment methods, effectiveness of the JOBS program and availability of child care facilities.

Finally, substantial funding has been requested to support our increasing computer technology demands. As a result of the our previous investment in technology and the associated productivity improvements, our budget reflects a $1,400,000 savings. However, funding is required to replace obsolete computer hardware and software as well as to expand our current system. The FY 1990 budget provides for the procurement of additional microcomputers and other ADP equipment for our employees, and a nationwide, departmental communications network. We have found that provision of adequate computer technology to our outbased employees reduces the delays in producing reports, improves communication, and increases productivity.

Funding spent on the Office of Inspector General is a sound investment. Over the past seven years, OIG has steadily increased productivity and has substantially increased the return to the taxpayer for each dollar invested in the OIG budget. These are statistics we are proud of, and intend to maintain. The $92,798,000 and 1,373 FTE we are proposing for FY 1990 will enable us to continue our accomplishments, and carry out our commitment to protect the Department's programs and the health and welfare of the beneficiaries of those programs.

BIOGRAPHY OF RICHARD P. KUSSEROW

Richard P. Kusserow was nominated Inspector General of the U.S. Department of Health and Human Services by the President in April of 1981 and confirmed by the Senate in June.

As Inspector General of the Department, he is charged with the statutory responsibility to ferret out fraud, waste, abuse and inefficiency in the world's largest agency. This department has some 250 health and human services programs and a budget of nearly one-half trillion dollars which represents over one-third of the federal budget.

Kusserow directs a staff of 1,400 auditors, inspectors, program analysts and investigators. His office recorded more than $5 billion in fines, savings, restitutions, recoveries and settlements in the last year. This represents a 3,500 percent increase during his tenure. Since 1981, convictions resulting from his investigative staff rose from 165 to nearly 1,300, an 800 percent increase. Additionally, he has increased successful administrative sanctions in excess of 1,000 percent against health providers and suppliers. He has "kicked out" over 2,500 individuals and entities from the Medicare and Medicaid programs for abusive or fraudulent behavior against the beneficiaries or programs.

Kusserow has served since 1985 as the Vice Chairman of the President's Council on Integrity and Efficiency (PCIE). The PCIE, created in 1981 by President Reagan, provides cohesive leadership to governmentwide activities to reduce fraud, waste and abuse in federal programs and operations. The Vice Chairman's role includes the responsibility for coordinating and tracking all governmentwide Inspector General projects; managing the preparation of the President's semiannual report on the accumulated accomplishments of all Inspectors General; coordinating efforts with the President's Council on Management Improvement; and, serving as liaison for all Inspectors General with the Office of Management and Budget.

He is a member of the Attorney General's Economic Crime Council and was appointed by President Bush to serve on the National Advisory Commission on Law Enforcement. Kusserow is president-elect of the National Association of Government Accountants (AGA) and past-president of the Baltimore Chapter of AGA. Since 1985, he has served on the AGA Task Force on Federal Financial Management. He also serves as the Federal representative to the National Intergovernmental Audit Forum. On July 1, 1987, he received the National Distinguished Leadership Award for sustained outstanding leadership and notable contributions in the field of financial management from the National Association of Government Accountants. He was twice elected national president of the Association of Federal Investigators and is an active member of the Society of Former FBI Agents, and the American Society of Industrial Security.

He earned his bachelor's degree from UCLA, followed by postgraduate work at Southern Methodist University and John Marshall University Schools of Law. He earned a master's degree from California State University at Los Angeles where he was also employed as a lecturer in government.

Kusserow served in the United States Marine Corps and was honorably discharged as a captain. He was an intelligence officer with the Central Intelligence Agency (CIA) before moving to the Federal Bureau of Investigation (FBI) in 1969. As an FBI agent, he worked in Pennsylvania, Washington, D.C., West Virginia and Chicago. He acted as the coordinating supervisor for nine squads of agents constituting the Chicago FBI Organized Crime program preceding his appointment as inspector general.

He has lectured widely and written numerous articles on innovative investigative and management techniques on fraud and corruption in government programs. He is author of a book entitled "Management Principles for Asset Protection."

TRANSUTANEOUS ELECTRICAL NERVE STIMULATOR [TENS]

Mr. KUSSEROW. Thank you, Mr. Chairman, and I will just make some highlights.

First of all, I think I might pick up where you left off. We just finished up a hearing a couple of weeks ago in which a significant part of the hearing dealt with seat lift chairs, which is really a chair not too much different from the chair you are sitting in. We were looking at whether the chairs are for medical use or whether they are used primarily for other purposes.

We thought that there were a lot of other purposes. A chairman sitting through a lot of long and hard appropriations hearings might be able to relax in it, or probably a more practical use would be as a witness chair. When you are finished with a witness the chairman could eject him.

But I was thinking that, here you are going hour after hour, day after day, week after week in appropriations hearings, and I thought another medical device might be worth looking at. You

might be able to find another use for this device. I brought a transcutaneous electrical nerve stimulator [TENS].

Senator HARKIN. Oh, really.

Mr. KUSSEROW. It is another medical device. Actually, you can get the component parts of this at Radio Shack for around $20. The cost of manufacturing a device like this might be about $85. On this particular device, Medicare is paying from $420 to $802.

Mr. Chairman, this thing has a 9-volt battery, and it has these little sensors. During these long, hard hearings you can test this and see if it has therapeutic effect, because as your back begins to ache you can turn this machine on.

Senator HARKIN. It vibrates a little bit?

Mr. KUSSEROW. Well, more than that. It electrically stimulates you.

Senator HARKIN. Oh, yes.

Mr. KUSSEROW. It also seems to me that your staff could be in charge of holding this thing, and if it looks like it gets too rugged and you are getting a little tired, you could be reactivated back into life by just turning up the volume.

You might want to look at this area, too, because it is another area of abuse.

Senator HARKIN. Let me see that. Now, you say this thing, the components cost about what, $20 maybe?

Mr. KUSSEROW. Well, if you paid for the component parts at Radio Shack, it would be about $20. If you are talking about the cost of manufacturing with the component parts, it is around $85.

Senator HARKIN. We are paying $600?

Mr. KUSSEROW. Medicare reimburses from $420 to as much as $802, with an average of about $480.

Senator HARKIN. Medicare does?

Mr. KUSSEROW. Yes; Medicare does. So it ranges enormously in price.

Senator HARKIN. How many of these do we buy every year?

Mr. KUSSEROW. Lots. It is one of the growth areas.

Senator HARKIN. All right.

Mr. KUSSEROW. In fact, Mr. Chairman, in about another month I can give you a draft report that we are doing as part of a survey of this entire system.

PRESCRIBING TENS FOR MEDICARE BENEFICIARIES

Senator HARKIN. Who is prescribing these?

Mr. KUSSEROW. Once again, it is the same modus operandi we had with the seat lift chairs, and that is the salesmen who work with doctors who virtually go door to door in neighborhoods of senior citizens asking Medicare beneficiaries if they have pain. These units are then prescribed for patients that answer yes. These can actually be used for a medical purpose and they do a good job, but that is not the point.

It is the marketing that we have some concerns about. That is where people go out and market these things by pressuring the elderly, or getting a compliant doctor to sign off on the item either sight unseen or after visiting the doctor. The salesman may say:

"Look, your patient wants this thing; you are not going to deny the patient the opportunity to have it?"

They are not really testing these things. These TENS units should be tested because they do not work on everybody. It might work on you, it may work on me, but it may not work on somebody else. The unit should be tested for 30 to 60 days before a decision is made to purchase it.

In the final analysis, it seems to me that we do not have the kind of controls that are needed. Once again, it is an area that lends itself to abuse. OIG is struggling with abuses of the Medicare system such as these.

Senator HARKIN. Excuse me for interrupting. Are there enough manufacturers out there to get competitive bids on something like this?

Mr. KUSSEROW. You can, of course. In fact, that is one of the problems that we have. About one-third of these devices are rejected each year for payment just on the basis that they do not meet standards.

You can see that it would not be that difficult for you and I to go after work tonight and pick up a bunch of parts and make an electrical device. Now, that can be dangerous, of course. What you may have is somebody with a pacemaker who really could not stand the voltage.

A lot of the TENS units really just do not meet the standard. They are not really approved by standards for payment. I think this just underscores what you had raised at the previous hearing, and I heard it again this afternoon.

We really need to take a close look at a lot of these durable medical equipment supplies and analyze how they are being marketed and how we are paying for them.

Senator HARKIN. If you could find out for me, I want to know how many of these things we buy.

Mr. KUSSEROW. Oh, I will. The fact is, I can give you a report on it. It is a moving target. It is a similar situation, Mr. Chairman, as we had with the seat lift chairs. We are finding that people run into a carrier that is doing the job and really screening hard, and then they go to another place where they have a carrier who does not have good payment controls. The end result is that you have people setting up shop in those areas and sending the bills through the compliant carriers.

Senator HARKIN. When are you going to have that report?

Mr. KUSSEROW. In about another month we should begin to have preliminary results coming back from the nationwide study that we are doing on this. I will be more than pleased to share the results with you.

Senator HARKIN. Come in and sit down with us. I would sure appreciate that.

FISCAL YEAR 1990 BUDGET REQUEST

Mr. KUSSEROW. With regard to our budget, we are requesting $92,798,000 in obligational authority. That does not include the fact that we do a lot of work for other agencies, about $1.5 million. That

is primarily as a result of the work that we do at the universities. We audit for other departments and we bill them.

We are requesting $49,498,000 in budget authority. We have a very substantial part of our activities in support of the Medicare, Social Security, and catastrophic health insurance trust funds. We have requested transfers in the amount of $43,300,000 from the trust funds. That includes the $3.3 million, as I mentioned, for the catastrophic health insurance trust fund.

The proposal for FTE's is 1,373. That is an increase of 15 over the current year, which I would mention is about 1 percent. The increase in obligation will be 4 percent, which is to cover inflation, built-in costs such as the January 1989 pay raise, FERS, rent increases, and so forth.

For the 6-year period from fiscal year 1983 through 1989, HHS program outlays increased about 56 percent, or roughly $150 billion, while during that same period of time, the Office of the Inspector General's budget and staffing decreased. I did not ask for any increase in staffing during those years.

But events have now taken place that suggest that we can no longer operate with limited resources. We are being spread too thin. This results from the fact that Congress has been very gracious in passing all kinds of new laws to assure that we have quality of care going to our beneficiaries and to sanction providers of health services, durable medical equipment producers, and other entities who would engage in fraud or patient abuse.

We are working in a lot more labor-intensive areas. Since I have been inspector general, 60 new administrative authorities have been enacted for us to enforce. These enforcement responsibilities do not result in a lot of statistics, but do ensure quality health care for our beneficiaries.

We continue during this year to have a payback of about $74 for every $1 invested in our budget.

Senator HARKIN. $74?

OIG PROGRAM COST SAVINGS

Mr. KUSSEROW. Yes; the cost savings of $5.56 billion for this last year were documented. We had the savings validated by the GAO, who did an audit of us, and we are pleased with our 97 percent rating. It is the highest rating we have ever received. I never got that high a grade in school.

GAO did not question the dollar results of the remaining 3 percent. They felt that we could have had stronger evidence to support the original recommendation which had been enacted by program officials.

This amounts to about $4.5 million saved for each OIG FTE. In addition to that, as a bonus, we prosecute wrongdoers who defraud our programs and beneficiaries. Last year we successfully prosecuted, through U.S. district court, 1,225 individuals and entities engaging in crimes against our programs and beneficiaries.

Senator HARKIN. Let me ask—you do not prosecute. You go to the——

Mr. KUSSEROW. The U.S. attorney prosecutes.

Senator HARKIN [continuing]. The U.S. attorney, and you provide the information?

Mr. KUSSEROW. We go to the Department of Justice, sir. And we have an investigative component for our programs.

In addition to that, we have administrative prosecutions. Last year OIG sanctioned 466 individuals and entities for engaging in fraud and abuse of the Medicare and Medicaid programs. This involves excluding those entities from our program for providing substandard care or for submitting false or fraudulent claims.

That also includes taking monetary action against them. Our basic philosophy is that no wrongdoer should emerge with unjust enrichment; regardless of whatever else happens to them, we want the money back. We do not want the program to suffer because they were able to cheat the system.

The 466 sanctions include both monetary penalties and exclusions from the Medicare and Medicaid program. Together, the successful prosecutions average out to a little over one successful prosecution per each OIG FTE. Our FTE's are divided into audit, investigations, and evaluation in the Office of Analysis and Inspections.

What I am saying is that I am taking the entire budget, all the FTE's, dividing it up and showing that you are getting some return for the investment you make with us.

AUDIT DIVISION FOR PHS

I would like to draw your attention to one of the things we have done, as promised before this committee last year. Due to the activity and the dynamic character of the Public Health Service and its various programs, which includes AIDS and biomedical research advances, and given the concerns about scientific misconduct and a whole host of other areas, I agreed that it was appropriate that we create a separate audit division that was devoted exclusively to the Public Health Service. This division would be put on the same level as the divisions which cover the Social Security Administration and the Health Care Finance Administration.

That indeed has been accomplished. That division is now operational, and we are now engaged full time with that division in focusing on all the programs of the Public Health Service, which include NIH, ADAMHA, FDA, CDC, the Commissioned Corps, HRSA, and all the other programs that are associated with the Public Health Service. We are not intermittent now; we are working full time in that arena, so that we can answer questions that may come up, both from the program officials as well as the Congress, regarding the effectiveness and efficiency of PHS program operations.

OIG PROGRAM EVALUATIONS

Another factor that has caused us to realign our resources and to continue the upward incline of our statistical results has been the need that both Congress and the administration have had in the area of evaluation: How well is a program working?

We now are doing, and have done for the past 3 years, client satisfaction surveys in Social Security. The survey asks the beneficiaries that go into a Social Security office or deal with Social Securi-

ty how they were treated, what problems they encountered, and so forth.

That has been so successful and useful that we are now doing surveys in the area of Medicare. We are doing client satisfaction surveys in the area of health maintenance organizations: How are our beneficiaries being served there? Are they satisfied with the quality of that program? There are a lot of questions that come up regarding it.

The area of evaluation very seldom comes out with any statistical results. It does provide useful information to help policymakers. It focuses on trying to understand what has happened in hospital practice since the advent of the prospective payment system.

We changed from a retrospective, pay-as-you-go system to one based upon diagnostic-related groups and payment on a prospective basis. What have the results of this been in terms of the practice of medicine?

In fact, the studies that we did, a series of studies, were so useful for the public needs that I had the unusual honor of being published in the New England Journal of Medicine. There are people in the Public Health Service that would give almost anything for the privilege of being in that very prestigious medical journal, probably the most prestigious in the world. And yet we were talking about what has happened to treatment with the advent of prospective payment.

The point that I would make along that line, Mr. Chairman, is we are finding that the character of our work is changing, the kind of people that we need is changing.

It used to be that we could go out and do an audit of a skilled nursing facility or a psychiatric facility and raise questions about payments. Not any more. Auditors cannot do that alone. Auditors must be out there, but they have to answer the questions for the grants appeals board and for policymakers regarding the effect it is having on the quality of treatment in those facilities.

Therefore, if we go into a psychiatric facility we have our auditors, but we need psychiatrists to see whether there is an impact as a result of poor practices on the quality of care being provided to beneficiaries.

If we are evaluating the quality of, let's say, coronary artery bypass grafts or open heart intrusive surgeries, then the grants appeals board wants to be sure that we have cardiac surgeons that are on our evaluation team. They do not think that auditors or investigators can do it by themselves.

We are being forced to rely more and more upon the health care specialists to be employed by the inspector general to carry out that kind of a request, and get away from our more stereotyped image of auditors with green eyeshades and garters on their sleeves and flat-footed, trench coated, cigar-smoking investigators.

We are getting into a much broader array of work because that is where the informational needs are. The end result is that it is really diversifying the kind of work that we are getting into and is spreading us thin.

This year we hope to continue to improve our statistical accomplishments. I do not mean to say that we are going to plummet. But I suggest that it is getting harder and harder to increase on

our current level of accomplishments as we devote more and more resources to the quality and effectiveness of program operations.

Therefore, I would summarize by saying that we are trying to be very, very modest in our current request. I went 5 years without ever asking for an additional FTE for our organization; in fact, OIG's FTE's actually decreased. I voluntarily reduced a number of FTE's when I came in in 1981 and again in 1982.

I find now, with our portfolio spreading wider and wider and thinner and thinner, that if I do not at least try to address some of the marginal pains that we are already suffering, I will not be able to continue reporting back to you high statistical accomplishments as well as evaluations on the quality and effectiveness of programs.

And with that, Mr. Chairman, I would be happy to answer any questions you might have.

OIG PROGRAM COST SAVINGS

Senator HARKIN. Mr. Kusserow, could you go back and review for me that $74 for $1? I do not know if I understand that.

Mr. KUSSEROW. Well, this last year, for example, we had $5.56 billion in fines, savings, restitution, and settlements for our Department's programs. If you divide our budget into that figure, that is the return on your investment in OIG.

Senator HARKIN. That is in fines?

Mr. KUSSEROW. Savings.

Senator HARKIN. Savings.

Mr. KUSSEROW. Savings, as well as restitutions, recoveries, and settlements.

Senator HARKIN. 5 point what?

Mr. KUSSEROW. $5.56 billion.

Senator HARKIN. Now, was that money actually recovered or would it be money that would not be—is it either money that was actually recovered or money that would have been spent had you not been there?

Mr. KUSSEROW. Well, it is both. In the areas where we have had audit disallowances sustained, the accounts recover the money. Fines are levied by the courts and the money comes in.

Settlements are where we have actually gone out and gotten the money back. That is, in the area of health providers that we find have abused the program and have engaged in unjust enrichment, we have monetary penalties. We sign settlements with them for return of the money. That is recovered; it is hard cash.

In addition to that, you have two other categories. For example, if we are looking at reimbursement rates, let us say on the end stage renal disease program, and we are able to demonstrate that, because of related organizations and so forth, you could reduce the amount of payments by x number of dollars, the recommendation goes into the Federal Register, the program agrees with the savings number, and that goes into the savings category.

The last category is in the Gramm-Rudman-Hollings base point reduction. That is where we oftentimes have to come to the Congress and say: This problem can only be solved with legislation. We think that if you were to take this action, you could effect savings without adversely affecting the quality of the program.

If we convince the administration to include the legislative proposal in the budget and Congress enacts it, then we claim savings based on the CBO savings estimate.

All of these types of actions account for the savings we claim.

Senator HARKIN. Good rundown.

Well, let me just compliment you on doing a fine job down there.

Mr. KUSSEROW. I do not know if I mentioned, Mr. Chairman, but on the seat lift chairs, subsequent to the hearing you did get the Health Care Finance Administration to agree that revisions were necessary to their existing policy. They are going to go ahead and do it; they promised it this next month.

Senator HARKIN. They are going to revise the policy?

Mr. KUSSEROW. HCFA is going to revise their policy and eliminate the routine payment for seat lift chairs. So on that round, score one for us.

Senator HARKIN. Good, good. Keep up the good work. Go after these things, too.

Mr. KUSSEROW. We are working on that, too. We will see what happens when that report is completed.

NIH PROCUREMENT REVIEW

Senator HARKIN. Good show. I just cannot emphasize how much—I really encourage you to keep going in this direction, well, for a number of reasons I have already stated.

Last year, you reported $26 million being wasted each year at NIH because of inefficient and mismanaged procurements.

Mr. KUSSEROW. That is correct.

Senator HARKIN. Your staff has been out to NIH to review the corrective program that NIH is putting in place. We have heard preliminary reports from your staff that there is not $26 million in wasteful spending, but a much smaller amount. I have asked you for a report as to how much you now believe can be saved.

Can you tell us now or how soon will you be able to tell us?

Mr. KUSSEROW. Well, I promised you that report by April 15 and I will take a risk here and see if I can give you our findings as of this moment in time. This is not the final but rather some preliminary results.

Basically, there are three component parts. One is open market purchases. There is about $64 million in open market purchases, where NIH did not fully utilize discounting. NIH was making major purchases and they were not taking full advantage of discounts.

NIH originally stated that they thought they were getting the discounts. We went out and found that, even when they thought they were, they were not always getting the discounts.

The NIH has been fairly aggressive in renegotiating those contracts. On the first round of negotiations they are getting about 8 percent reductions. That looks promising. Now, at 8 percent, which I think is a good starting point—I do not want to suggest that I think that it is an ending point—that would bring it about $5.1 million in savings on that first $64 million.

Now, I believe that one can continue to negotiate from that point and NIH could probably bring it from the 8 percent up to 15 percent, which would generate savings of almost $10 million.

There are two other component parts, much of which NIH has not yet addressed. The lack of attention is because they have not really been convinced that it warrants priority, but I think it does. There are a certain number of vendors that deal with Federal supply schedule items. What they are saying is, we are paying the Federal supply schedule and, therefore, you cannot reduce that cost.

Well, that is right. The problem is you may have a Federal supply schedule vendor who has 1,000 items, but only 100 of them are on Federal supply schedule and 900 are not. NIH is paying retail on the 900. We believe that NIH should pay Federal supply schedule for that which is a negotiated rate, but on everything else they should again use the leveraging power of major purchases to reduce the cost.

We feel that, depending upon the ratio between the Federal supply schedule items and the non-Federal supply schedule items, which we will still have to verify through audit activity, that savings will be somewhere between an additional $2.6 and $5.2 million.

The third area where NIH is not really convinced that effective reductions can be obtained, and I just refuse to accept this, is in the area of services. There are a great number of consultant services contracts that are granted without competition.

We feel that NIH could save money on some of these contracts if they were competitive.

There is also a very large portion of the $62 million in services, $24 million to be exact, which is in the area of utilities. NIH is saying that they cannot negotiate rates with companies like Pepco and AT&T and so forth. I disagree with that.

Once again, until I have our auditors go talk to those vendors of utility services, I can't speak definitively. But I believe that significant discounts could result in savings in the neighborhood of between $3.8 and $6.2 million.

NIH PROCUREMENT SAVINGS

All told, Mr. Chairman, savings on this first round effort depend on whether you want to take the most conservative of the estimates or take what I think is a more realistic estimate. I think we can do better than what the conservative estimates are. We estimate the savings to be somewhere between $11 and $21 million.

I do think that we can effect more savings. On this report, the longer I have to analyze the numbers, the more accurate will be the report. I think the total savings will be closer to the high end of the range.

I remember it was not so long ago that Mr. Natcher on the House Appropriations Committee heard the same story about utility discounts in the District of Columbia. After a couple of words from him, we suddenly saw that the District of Columbia started getting better prices.

I have an inclination that maybe these big companies out there can, in fact, give us a good deal if we spend a lot of money with them.

DEPARTMENTAL LOGOS, SYMBOLS, AND EMBLEMS

Senator HARKIN. Good.

I am going back to your testimony here, written testimony. You said: "Under the authority of the catastrophic law, OIG will promulgate regulations implementing sanction provisions relating to the misuse of departmental symbols and emblems which might be used to inappropriately convey Federal support of private sector programs."

Mr. KUSSEROW. I think you alluded to it in passing, that a lot of people are out there talking to your constituents. They are providing information, and sounding very authoritative, which they may or may not be.

Whether they are authoritative or not is not important. However, they should not in any way convey that they are the Federal Government or have the approval or endorsement of the Federal Government. So one of the things that Congress put in the catastrophic health insurance legislation was a safeguarding of the program logos, the program names, and so forth.

And a major responsibility for implementing those regulations falls upon me.

Senator HARKIN. I would be interested in what you are looking at there. It is not against the law now to put "Social Security" on the outside of an envelope, is it, by a private company?

Mr. KUSSEROW. Yes; the Social Security emblem is, in fact, protected.

Senator HARKIN. The emblem. I am talking about the words, "Social Security."

Mr. KUSSEROW. No; that is correct. If you say "Social Security Administration" and you use the logo of the Social Security Administration, yes.

Senator HARKIN. Yes; but if I sent a mailing and on the outside I say——

Mr. KUSSEROW. Citizens for Social Security.

Senator HARKIN. Or "important Social Security information inside."

Mr. KUSSEROW. That is right.

It is a tricky area for obvious reasons, because you do not want to deny public interest groups an opportunity to educate the public. But again, going back to what I heard you say earlier with Dr. Sullivan, there is maybe not a suspicion, but a concern that some of these groups have motives that are not quite altruistic, especially when they ask for money.

Senator HARKIN. That is right, exactly. Well, I would like to see what you are doing. If there is any need for legislative reform, we ought to know that, too.

Mr. KUSSEROW. Well, I think that you have made some legislative reform. I think it is a question of whether we can implement your intent.

Senator HARKIN. I know I talked to Senator Heinz about this in the past, too.

Let us see.

MEDICARE SECONDARY PAYOR

Mr. KUSSEROW. Mr. Chairman, you did raise one point with Dr. Sullivan that maybe I can discuss. You referenced the article in the Washington Post regarding the Medicare secondary payor issue.

Senator HARKIN. Yes.

Mr. KUSSEROW. Dr. Sullivan mentioned that we were working on that issue. The Department of Justice issued a press release on the action that they have taken against Provident and we are working on others.

We are the investigator for the Department of Justice on this issue. We were conducting the investigation and our auditors were auditing whether that particular health insurer had not, in fact, followed the law, in that they should have been primary payor in some of these cases. They were allowing Medicare, the secondary payor, to be the primary payor.

The point that had been raised was how many other health insurers might be so similarly engaged. I think an even more cogent point would be whether it is possible that people we have a fiduciary relationship with, health insurers who are also contractors, might be violating their fiduciary responsibility. On the one hand, they are acting as an agent of Medicare, and then on the other hand they may be bilking Medicare.

This is an area that we are working on, and devoting a great amount of resources to. We want to see if it is a major problem, how much money is involved and how to get that money back. If it was fraudulent abuse, we will see if we can give the perpetrators a one-way ticket to a Federal facility.

Senator HARKIN. Is this investigation going on right now?

Mr. KUSSEROW. Oh, it is massive. It will be a long time before it comes to resolution. I want to tell you, Mr. Chairman, an audit of a major health insurance company is no small undertaking.

I would remind you that we have 700 auditors. It is sort of like a platoon of marines trying to occupy mainland China. It is a big undertaking.

Senator HARKIN. The marines could do it, though. [Laughter.]

And I know you were in the marines.

Mr. KUSSEROW. Sometimes when you are told to take the hill, you do not know whether you want to believe the propaganda or your own inner fears.

Senator HARKIN. Well, keep us advised on that.

Mr. KUSSEROW. We will indeed.

ADAMHA FUNDING

Senator HARKIN. You saw me raise with the Secretary the issue on the Alcohol, Drug Abuse, and Mental Health Administration funds and things like that.

Mr. KUSSEROW. Yes; I was tempted to mention that issue which had been raised last year to Dr. Bowen. We wanted to find out

whether it was true that States were having a problem figuring out how to spend the money, and indeed we did study that subject.

I think that as a result of the commentary that took place between you and Secretary Sullivan, I have a suspicion that I am going to be back on the street again this year to find out——

Senator HARKIN. That is just what you need, some more work to do.

Mr. KUSSEROW. Well, we will try to get some more information, try to get a better understanding about the problems and the causes of the delay on the drawdowns.

Senator HARKIN. Again, find out what the heck is going on out there.

Your office also, in the same vein, recommended that they develop a strategy to evaluate the effectiveness of drug education programs. I am very interested in drug education programs. You heard me state that. But I also want to make sure that they are effective, that they are good drug education programs.

And are you saying that they do not even have a strategy to evaluate whether they are effective?

Mr. KUSSEROW. No; I think the problem here, quite frankly, is that it has taken time for the States to develop the programs.

The evaluation that Dr. Sullivan was referring to is not being done by our office. That is going to be done by a separate evaluation study.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. We will just submit the rest of these questions, the ones I wanted to ask for the record, Mr. Kusserow.

Mr. KUSSEROW. Fine. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

NIH PROCUREMENT REFORMS

Question. Mr. Kusserow, last year you reported that $26 million is being wasted each year at NIH because of an inefficient and mismanaged procurement system.

Your staff has been out to NIH to review the corrective program that NIH is putting in place. We have heard preliminary reports from your staff that there is not $26 million of wasteful spending going on but a much smaller amount.

As you know, I have written you and asked for your report by April 15 as to how much you now believe can be saved.

What can you tell us?

Will we be able to capture $26 million of wasted procurement spending in the fiscal year 1990 appropriations bill so that we can fund important biomedical research, or not?

Answer. As of mid-April, the OIG completed audit work to determine the range of annual savings which NIH should achieve once it completes its three-year program of procurement reforms in its delegated procurement small purchasing system (DELPRO). We estimate that NIH could save between $10 million and $15.3 million annually when these reforms are fully implemented. NIH believes that savings will be lower -- $6.6 million to $9.1 million. Based on preliminary information provided by NIH, we believe that NIH could achieve an additional $3.6 million to $5.9 million in savings in its two other small purchasing systems: centralized procurement and decentralized purchasing offices.

As stated previously, our estimated range of annual savings is based on NIH's full implementation of its planned procurement reforms. However, at the end of September 1989, NIH will be only one year into its three-year reform plan. On this basis, we estimate that for FY 1990, NIH could possibly save between $3.3 million and $5 million. This estimate assumes that NIH expedites completion of a greater number of negotiations for vendor discounts and competitive solicitations, as recommended in our March 24, 1989 report.

FRAUD AND ABUSE IN BOARD AND CARE HOMES

Question. Recent studies have focused attention on fraud and abuses in board and care facilities, including alleged profiteering of operators by diverting Supplemental Security Income (SSI) funds to their own personal use.

What can you tell us about the extent of fraud and abuse in board and care facilities?

How well staffed is the Inspector General's office to aggressively monitor, investigate, and prosecute cases of fraud, abuse, and neglect in board and care homes?

Answer. We are planning an inspection to address recent Congressional concerns over the selection of representative payees. The inspection will examine the availability of qualified representative payees for eligible individuals who have no family or friends who are willing to serve as payees. The beneficiary population for this inspection will include, but not be limited to, residents of board and care facilities.

In addition, we are conducting a study of State and local regulation of board and care homes. Given the numbers of such homes and variations in State and local codes governing them, we believe the States and individual localities can more appropriately regulate in this area.

CATASTROPHIC HEALTH

Question. Mr. Kusserow, your office has planned a number of studies associated with the Medicare Catastrophic Coverage Act of 1988, including reviewing the controls built into the new benefit system.

Can you report on the progress to date on reviewing this law?

Answer. OIG has a number of reviews underway, evaluating many aspects of the law as it phases in new Medicare benefits through 1991. For example:

Part A Systems Reviews - OIG auditors assessed the operational readiness of a representative sample of Part A fiscal intermediaries to correctly process the expanded Part A benefits authorized by the law effective January 1, 1989. Because the new benefits necessitated changes in the claims processing systems of all Part A intermediaries, these changes had to be designed, tested and implemented by early January 1989. The audit concluded: the sampled intermediaries were operationally ready to process the new Part A benefits based on their successful processing of 15 test claims developed by HCFA. But, HCFA could have provided more timely and thorough instructions to the intermediaries on the process for testing their systems changes.

Procurement Planning for Point-of-Sale Network - This on-going review is evaluating HCFA's implementation approach to the mandated electronic point-of-sale network for processing pharmacy claims on and after January 1, 1991. We are evaluating whether HCFA's planned approach is consistent with the law, whether it is the best alternative in terms of efficiency and costs and whether the planned network procurement is on schedule for January 1, 1991. Our tentative conclusion: HCFA's approach is consistent with the law, but alternative models may be more efficient and less costly. Also, the procurement schedule is so tight that schedule relief may be needed from the Congress.

Our assessment is that we are making good progress in evaluating the law.

We have also begun work on a number of inspections pertaining to the outpatient drug benefit contained within the Medicare

Catastrophic Coverage Act of 1988. These inspections and their current status are as follows:

Medicare Drug Utilization Review - This inspection documented that there is a widespread problem of mismedication among older adults. We are concerned that when the outpatient drug benefit is implemented, the use of prescription medications by older adults may increase and cause an increase in the number of adverse drug reactions among the elderly. In our report, we recommended that:

- The Health Care Financing Administration should begin the development of a comprehensive drug utilization review program designed to promote quality of care, control program costs and ensure program integrity.

- The Health Care Financing Administration and the Public Health Service, individually and collaboratively, should promote improvements in the prescribing, dispensing, and utilization of drugs for older adults by making funding available to finance research that will test drug utilization review interventions and evaluate their relative costs and benefits and also that they develop drug utilization review criteria that will serve as a national standard for drug utilization programs conducted throughout the country.

Pharmacist's Counseling - We are now in the planning stages of an inspection to examine approaches for improving the activities of pharmacists to counsel beneficiaries regarding appropriate administration of the drug, potential side effects and related therapeutic issues. We will also examine approaches for pharmacists who identify a potential drug reaction to resolve these problems through consultation with physicians and patients before dispensing the drug.

Medication Regimens - We are now planning an inspection which will examine the causes of non-compliance with prescribed drug regimen among elderly patients. In addition to documenting the causes of this problem, we intend to suggest approaches for improving education of patients regarding the need to carefully comply with prescribed drug regimens or to resolve their problems through consultation with pharmacists and prescribing physicians.

Question. What conclusions have you drawn about the fairness of the law's financing mechanism?

Answer. Our studies to date have identified one area of the financing mechanism for the Catastrophic Coverage law that we consider not to be fair or equitable. The Medicare Catastrophic Coverage Act of 1988 provides that the supplemental premium is to be based on an individual's Federal income tax liability. Because this liability does not include taxes on tax-exempt interest, individuals can avoid the premium on that interest income. Not only will the loophole cause the program to lose revenue, it is unfair to less affluent and financially knowledgeable individuals who do not own tax-free investments and are not able to avoid the premium.

Furthermore, allowing tax-exempt interest to escape the supplemental premium is not consistent with the Federal

Government's policy on taxing Social Security benefits. For these benefits, tax-free interest must be included in determining how much of the benefits are subject to taxation.

It does not appear that Congress considered the tax-free income issue in deciding how the supplemental premium would be figured. In a recently released draft management advisory report, we recommended that HCFA propose legislation to close this loophole, by amending the Act to include tax-exempt interest in determining an individual's supplemental premium.

FULL-TIME EQUIVALENTS

Question. Your office added 49 FTE positions this fiscal year for increased responsibilities brought about by the Catastrophic Coverage law. Your budget requests an additional 15 FTEs next year for these same responsibilities.

Have your responsibilities increased since the 49 positions were added? Why do you need 15 additional positions?

Answer. The FTE increases requested for FY 1989 and FY 1990 have been and will be used to meet legal and programmatic responsibilities which have been added in recent years. Many of these additional responsibilities were brought about by the enactment of the Medicare Catastrophic Coverage Act of 1988. The substantial increase in Federal Medicare expenditures for catastrophic health care will impose significant additional oversight, enforcement and evaluation responsibilities on the OIG. These oversight and enforcement activities begin immediately with implementation of the catastrophic legislation.

The OIG's oversight and enforcement responsibilities have been increased under the Medicare Catastrophic Coverage Act. To date, we have plans for over $2.5 million in personal services monies which will provide support for 49 FTE in 1989. In addition, funds are targeted towards a number of contracts, inspections and investigations, including a study on baseline drug utilization, drug industry financial and a joint contract with HCFA. The funds, most of which are allotted, total $695,000. The OIG will review internal controls built into the benefit system, identify individuals who access the program in a manner or volume that differs substantially for prior or acceptable practices, identify individuals and entities who might be predisposed to take advantage of the new program, and identify unintended escalation of program costs so that adjustments can be made. A portion of the FY 1989 FTE increase was also used to hire investigators so these individuals would be in place once the law was enacted and implemented. The OIG's monitoring activities will likely increase in FY 1991 when the prescription drug benefit is phased-in.

In recent years, the OIG's workload and responsibilities have increased while OIG staffing has been reduced. From FY 1983 to FY 1988, the OIG budget decreased by 137 FTE, or 10 percent. During this period of time, HHS program outlays increased by 39

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percent ($107 billion). There is an inherent increase in the demand for OIG audits and inspections with an increase in program outlays. Other events have also increased our responsibilities. These events include the passage of 60 administrative civil money penalty (CMP) and sanction authorities during the past four years (14 of these authorities were included in the Catastrophic law). In FY 1990, we will continue to expand our oversight of AIDS-related activities to include monitoring the use of research and educational funding, monitoring the safety of biomedical laboratory research, coordinating efforts within HHS under various contracts and research efforts, and analyzing the appropriateness and cost of care for AIDS patients. Other responsibilities include inspection and investigative activities relating to scientific misconduct, monitoring of the implementation and effectiveness of the Family Support Act of 1988, and oversight of clinical laboratories.

In summary, the increases in FTEs have been necessary to enable us to meet a number of responsibilities which we would not have been able to have met without the FTE increase. These include elimination of a workload backlog which resulted from increased program outlays, implementation and enforcement of new administrative authorities, and monitoring activities pertaining to recently enacted legislation. The FY 1990 FTE request will enable us to conduct monitoring activities which pertain to the Catastrophic law and meet our other programmatic and statutory responsibilities.

HOSPITAL EQUIPMENT COSTS

Question. According to a recent study, hospitals will spend $8.3 billion on equipment in 1989, an increase of 7.6 percent over last year. They already spend almost two-thirds of their equipment budget on high-tech gear, and the largest piece of the pie is diagnostic-imaging gear, which is the most expensive equipment around.

I'm disturbed by two elements of this type of buying. The study said hospitals that forego purchases of high-tech equipment to save $100,000 -- most rural hospitals have to do this -- may lose $1 million in patient revenues as a result. Another disturbing element identified by this study is that a major factor affecting purchasing decisions is "keeping up with the Joneses," the hospital down the street.

Has the IG done any studies on the impact of this high-tech race on rural hospitals, which don't have the same access to capital for large equipment expenditures?

Has the IG looked into how we can encourage hospitals to maintain their facilities without buying equipment simply to win the high-tech race?

Answer. An OIG study of hospital closures has identified the lack of capital for modern equipment purchases as one of several factors contributing to the closure of rural hospitals. However, we have not specifically studied the impact of the high-tech

equipment race on rural hospitals or looked into how they could be encouraged to maintain their facilities without buying equipment simply to win the high-tech race.

EFFICIENT HOSPITAL CARE

Question. We have heard a lot about how Medicare pays rural hospitals about 40 percent less than urban hospitals for an average case. I believe this urban-rural differential is a major cause of rural hospitals' problems with the Prospective Payment System. Some people say that rural hospitals' problems stem from a low volume of patients, and say that the number of empty beds in rural hospitals proves they are less efficient.

But given that urban hospitals cost so much more for treating Medicare patients than rural hospitals, isn't it more efficient to treat patients at rural hospitals?

If rural hospitals will continue to close, Medicare beneficiaries who live in rural areas will have to go to urban hospitals for treatment, and urban hospitals are reimbursed at much higher rates than rural hospitals. What will be the impact of more rural hospital closures on Medicare expenditures? Is this an efficient way to manage Medicare or deliver health services?

Answer. The premise of these questions is that, when rural hospitals close, Medicare patients must utilize higher reimbursed urban hospitals for treatment, increasing Medicare expenditures. Our studies indicate that this is not always the result. During 1987, several of the rural hospitals that closed were located near other community hospitals which assumed the patient load of the closed hospitals. Therefore, Medicare expenditures were not increased in these cases.

Where sole community hospitals close in rural areas, Medicare costs may increase if patients have to utilize urban hospitals. However, the typical rural hospital closure involves a 43 bed facility with 21 percent occupancy, a patient census of nine and a Medicare patient census of four. Providing a subsidy to keep these small, under-utilized facilities open may be more costly than the alternative use of urban hospitals.

NEW HOSPITALS

Question. The Administration has made a concerted effort over the last several years to close hospitals and reduce excess capacity. I think there's been a lot of trouble aligning that theory, which is a good one, with actual practice. I'm convinced that our PPS system isn't closing the right hospitals.

But I want to raise the issue of new hospitals. In 1988, 58 hospitals opened. Three-quarters of them were psychiatric and rehabilitation hospitals, two groups that are exempt from PPS.

Has your office traced the growth in these exempt hospitals since prospective payment to hospitals started?

Answer. We have initiated a two-phase review of hospitals and units which are exempt from Medicare's prospective payment system (PPS). In the first phase, we will identify the types of units and hospitals which are exempt, and obtain cost and revenue information on them. We will then identify and evaluate current methods of assuring that payments to these entities are reasonable. We will also evaluate other studies pertinent to care provided by these facilities.

In our second phase, we will evaluate the effectiveness of existing control mechanisms (e.g., peer review organizations, UR activities, facility audits, etc.). We will use existing data bases to compare treatment indicators (e.g., length of stay) for various groups. We will also determine the feasibility of using control mechanisms which have proven successful in other patient care settings.

DRUG MISUSE IN NURSING HOMES

Question. A recent study by medical researchers indicates that 40 percent of nursing home residents are given anti-psychotic drugs intended for treatment of severe mental illness. These drugs can be fatal, especially to the elderly. According to your office, those age 60 and older account for 39 percent of hospitalizations and 51 percent of the deaths from adverse drug reactions.

What studies have you conducted and what recommendations have you made to reduce the incidence of misuse of drugs?

Answer. The statistics that you cite concerning the adverse drug reactions and other mismedications among the elderly were developed in our recent report entitled "Medicare Drug Utilization Review." In a related inspection now underway, we are examining the physical abuse of patients in nursing homes. One of the major issues in this inspection concerns whether or not there is a misuse of chemical restraints including the anti-psychotic drugs that you mentioned. Our report will examine the perspectives of health care administrators, nursing home employees, and law enforcement officials concerning the reporting and resolution of complaints of patient abuse in nursing homes. We would be happy to share with you our report when it is completed.

Question. Who is conducting oversight of the use or misuse of drugs among nursing home patients?

Answer. HCFA regulations implementing the Omnibus Budget Reconciliation Act of 1987's nursing home reforms require that nursing home patients' drug regimens be free of unnecessary drugs, significant medication error rates, and clinically unnecessary anti-psychotic drugs. This rule becomes effective in August 1989; the requirement will then be subject to review as part of HCFA's survey and certification process for nursing homes. In addition to the study of abuse of nursing home patients discussed above, we are proposing a FY 1990 study of the use of medications by nursing home patients which will assess implementation of the new regulatory provisions.

FRAUD AND ABUSE REGULATIONS

Question. Your office has proposed Medicare Fraud and Abuse regulations that would severely limit referral relationships between hospitals and physicians. I'm concerned about the impact these regulations might have on doctors in rural areas.

In many rural areas, the issue isn't competition but rather access to care. There are already 1292 rural health manpower shortage areas requiring 1792 physicians. And the situation is likely to worsen: a recent study indicated that up to 25 percent of rural physicians may retire or leave their communities within five years.

If a hospital's support can help stabilize a physician practice, that will keep the doctor in the area. And that's good for the hospital.

Is your intent that the regulations would outlaw all financial arrangements between hospitals and physicians, or will there be an exemption for hospitals and physicians that are not in a competitive market?

Answer. The intent of our proposed regulations addressing the Medicare anti-kickback statute is to specify those various payment practices which, although potentially capable of inducing referrals of business under Medicare, would not be considered kickbacks for purposes of criminal prosecution or civil remedies. Specifically, the proposed regulations implement sections 2 and 14 of Public Law 100-93. Section 2 provides the OIG new authority to exclude a person or entity from participation in the Medicare and State health care program if it is determined that the party is engaged in a prohibited remuneration scheme. Section 14 requires the promulgation of regulations that specify those payment practices that will not be subject to criminal prosecution under section 1128B of the Social Security Act and that will not provide a basis for exclusion under section 1128(b)(7) of the Act.

We are aware of the unique position which physicians occupy in the medical marketplace and which has led to the examination of their relationship with varying business arrangements. It is the physician who controls access to a large array of medical items and services in order for third party reimbursement to be available. This is a highly competitive market that is constantly expanding, and while this competition is important, it is necessary for the fiscal integrity of our programs to assure that physicians exercise sound, objective medical judgment when controlling admittance to this market. We have attempted in our proposed regulations to permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy. At the same time, we have included in these proposed regulations various added criteria to each of the "safe harbor" provisions in our effort to reduce the potential for fraud and abuse against the programs and their beneficiaries.

EFFECTIVENESS OF DRUG EDUCATION PROGRAMS

Question. Your office recommended that the Alcohol, Drug Abuse, and Mental Health Administration and the Department of Education develop a strategy to evaluate the effectiveness of drug education programs.

Has an adequate strategy been developed?

What kind of evaluations are underway, and what have they shown about the effectiveness of current programs?

Answer. The Alcohol, Drug Abuse and Mental Health Administration (ADAMHA) has been working with the Department of Education (DEd) to develop evaluation strategies for drug education programs. ADAMHA has transferred $250,000 to DEd to expand the evaluation of programs funded under the Drug Free Schools and Communities Act. The High Risk Youth Demonstration Program will be covered by this evaluation activity. This study is scheduled for completion in April 1990. Because the recommended evaluation activity primarily involves longitudinal studies, we would not expect specific data on effectiveness at this time. As the evaluation activity proceeds, our oversight of this area will continue, and we will develop plans for follow-up studies in late FY 1990 or 1991.

SUBCOMMITTEE RECESS

Senator HARKIN. Again, my compliments to you, Mr. Kusserow, and I really hope that we have an open line of communication with you from our staff to your staff level. And any time I can be of assistance, let me know.

Mr. KUSSEROW. Well, if the appropriations process is as painful as it looks to a casual visitor, I will get you a TENS unit that actually functions the way it is supposed to. You can give your own testimonial one way or the other.

Senator HARKIN. Yes; for $85, please. [Laughter.]

Mr. KUSSEROW. Yes; thank you, Mr. Chairman.

Senator HARKIN. Thank you.

The subcommittee will stand in recess until Wednesday, April 12, at 9:30 a.m., when we will continue our Department of Health and Human Services hearing in room 138.

[Whereupon, at 3:18 p.m., Monday, April 10, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, April 12.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

WEDNESDAY, APRIL 12, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:03 a.m., in room S–126, the Capitol, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, and Cochran.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF LOUIS B. HAYS, ACTING ADMINISTRATOR

ACCOMPANIED BY:

LEE MOSEDALE, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT AND PROCUREMENT

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DHHS, ASMB

BARBARA GAGEL, DIRECTOR, BUREAU OF PROGRAM OPERATIONS

PREPARED STATEMENT

Senator HARKIN. The Subcommittee on Labor, Health and Human Services, Education and Related Agencies will come to order.

Today we will hear testimony from the Health Care Financing Administration and the Social Security Administration for the President's fiscal 1990 budget request. These two agencies represent an enormous and growing slice of the trillion dollar Federal budget. The Social Security Administration includes $250 billion in expenditures for old age, survivors, and disability benefits; and the Health Care Financing Administration includes $133 billion for Medicaid and Medicare.

At the outset I want to state that I am committed to protecting every legitimate benefit to which the poor, the elderly, the sick, and the disabled are entitled to under these programs. At the same time the need to reduce the Federal deficit means we must do all we can to root out wasteful or fraudulent spending in these massive programs.

In the Health Care Financing Administration, I want to examine wasteful expenditures for duplicative computer systems of our Medicare contractors. Addressing this problem can save us, I am told, $15 million in fiscal year 1990.

I also want to discuss exorbitant fees paid to suppliers of oxygen and ambulance services where hundreds of millions could be saved each year.

I will point out allegations of excessive payments to health maintenance organizations and Medicare funds wasted on poor quality health care.

In the Social Security Administration, I am concerned we are not getting our money's worth for an expensive new telephone system. Social Security clients get busy signals 30 percent of the time on this new system and have excessive waits before being served, only to get wrong answers 30 percent of the time.

I am also distressed that it frequently takes 6 months for elderly and disabled persons to get a hearing date scheduled when they appeal rulings by the Social Security Administration. Hopefully, we can do better in addressing the needs of our elderly for due process and fair and timely hearings.

First off, we will hear from Mr. Lou Hays, Associate Administrator for Operations at the Health Care Financing Administration. Mr. Hays, I must tell you that from the time that I have spent as chairman of the subcommittee, there appears to be plenty of room to reduce spending before we have to start cutting back on some of the essential payments suggested in the budget which you have sent up to us, such as Medicare payments to hard pressed rural hospitals. Every dime we save helps hold down premiums and co-payments for Medicare beneficiaries.

This would conclude my openings remarks. At this point I will leave the record open for any opening comments by members of the subcommittee and especially Senator Specter, ranking member.

Mr. Hays, we will put your entire prepared statement in the record. To save time I will ask you to briefly summarize it.

[The statement follows:]

STATEMENT OF LOUIS B. HAYS

Mr. Chairman and Members of the Subcommittee, I am honored to be here today to present the Fiscal Year 1990 budget request of the Health Care Financing Administration. As the new Acting Administrator of the Federal agency that administers $133 billion annually in health care spending, I could not be more aware of the challenges currently faced by both the Congress and the Administration in slowing the growth of health care expenditures without compromising the quality of medical care. We have already taken the first steps down that road with the submission of President Reagan's Fiscal Year 1990 Budget in January and then the refinements to that budget announced by President Bush on February 9.

In "Building a Better America," the Bush Administration made a commitment to hold the increase in Medicare, the fastest growing entitlement in the Federal budget, to $10.1 billion from FY 1989 to FY 1990. This represents a 10 percent increase in Medicare spending for 1990, compared with a 14 percent increase that would occur without the reforms proposed.

President Bush's Medicaid proposals embody the spirit of a government with a more human face by maintaining funding for the Medicaid program at the current services level, and proposing expansions of coverage and benefits for pregnant women and children. These improvements in Medicaid would be financed through reductions in obsolete special match rates for administrative expenses.

With respect to the discretionary accounts that fall within the purview of this committee, the Bush budget proposes a "flexible freeze", under which aggregate spending would be held to the FY 1989 level. However, increases in some accounts could be offset by decreases in others. We expect the precise funding mix to emerge through negotiations between the Administration and the Congress. As a point of departure for these discussions, we will begin with the amounts requested for each account in the Reagan budget.

At this point I would like to highlight each of the appropriated accounts within the HCFA Fiscal Year 1990 budget request.

Grants to States for Medicaid

Medicaid will help finance needed medical care for an estimated 26 million low-income people in the coming fiscal year, including 550,000 qualified Medicare beneficiaries. The Bush budget requests $37.6 billion for the Federal share of benefits and administration of Medicaid in FY 1990, a $3.3 billion or a 9.7 percent increase above our current outlay estimate for FY 1989. This FY 1990 request assumes that the Federal government will be providing nearly 56 percent of the total $67.3 billion projected for Federal, State, and local expenditures under the Medicaid program in FY 1990. Our proposed law estimate for Medicaid is the same, since the costs of improving benefits would be offset by the savings associated with our proposal to reform administrative costs matching rates.

Payments to the Health Care Trust Funds

The account designated "Payments to the Health Care Trust Funds" encompasses various sums appropriated to the Medicare trust funds, but consists almost entirely of the Federal general revenue subsidy of the Supplementary Medical Insurance (Part B) program. Federal general revenues currently finance 75 percent of Part B program costs. Our Fiscal Year 1990 request for this account is $36.3 billion, a $5.1 billion or 16.4 percent increase over the Fiscal Year 1989 amount. These figures do not reflect our proposed legislative extension of: (1) the provision under which the premium is set at 25 percent of aged program costs, which would save $617 million in FY 1990, or (2) current carrier-wide limitations on payments for clinical laboratory services, which would save $190 million. The increase in the Federal contribution to Part B reflects rapid growth in Part B program costs.

Program Management

Through its program management accounts, HCFA oversees the administration of both Medicare and Medicaid, monitors the quality of services provided to beneficiaries, conducts policy relevant research, and funds the claims processing and review activities of the fiscal intermediaries and carriers. The total FY 1990 request of $1.9 billion is made up of $0.1 billion appropriated from general funds and $1.8 billion authorized to be transferred from the Medicare trust funds. Amounts are requested for the following activities:

Research

We are requesting $37.0 million to fund research, demonstration, and evaluation activities in FY 1990, a 26.8 percent decrease in the amount appropriated for these activities in the current fiscal year. The major reasons for this decrease are: (1) the one-time costs associated with a Congressionally mandated rural health demonstration, and (2) one-time costs of the start-up of catastrophic health insurance studies, both of which made the FY 1989 figure unusually large. The amount we have requested for FY 1990 includes:

- $19.4 million for physician/provider payment reform and refinement studies;
- $8.8 million for quality of care projects;
- $3.0 million for studies associated with catastrophic health insurance; and
- $2.5 million for research in the areas of long-term care, subacute care, and utilization of services.

Nearly $21 million, or 56 percent, of this budget represents continuation of Congressionally-mandated studies.

Medicare Contractors

Through the Medicare Contractor budget, HCFA ensures that beneficiaries receive prompt, accurate and courteous service on their claims; providers and suppliers are treated fairly consistent with law and regulations; and taxpayer dollars are conserved through payment safeguard activities. The contractor budget provides funding for the operating costs incurred by the private firms that assist HCFA in administering the Medicare program. The Administration's FY 1990 budget includes $1.4 billion for the Medicare contractor activity, plus a $100 million contingency reserve. The requested level is only $77.4 million above the FY 1989 appropriation -- a 5.7 percent increase.

As former Acting Administrator Terry Coleman explained to this subcommittee at an earlier hearing in February, this modest increase in contractor funding necessitated hard choices. Our priority had to be to provide adequate funding to the claims processing and beneficiary inquiry functions, especially given the importance of catastrophic implementation. We expect both claims volume and beneficiary inquiries to rise sharply as beneficiaries become eligible for the new benefits under the catastrophic law. Thus, reductions will be required in spending for payment safeguard activities. In a less constrained budget environment, we would have maintained and probably even expanded medical review, provider audit, and medicare secondary payer review because they have been demonstrated cost effective. For every dollar we spend on payment safeguards, benefit outlays are reduced by $7 to $21.

State Survey and Certification

Through the State Survey and Certification program, HCFA ensures that facilities participating in Medicare and Medicaid meet certain quality and safety standards.

Institutional and non-institutional providers of health care services to beneficiaries are surveyed before they are permitted to participate in the program and periodically thereafter to demonstrate continued compliance with program rules. We are requesting a total of $174.3 million for this activity in FY 1990. In addition to the $75.3 million for Medicaid survey and certification which is included within the Grant to States for Medicaid request, we are also requesting $99.0 million for Medicare State Survey and Certification.

Our budget calls for a $31.7 million or 47.0 percent increase in Medicare State Survey and Certification activities relative to the amount appropriated for FY 1989. This increase is needed in order to continue ongoing survey activities and to carry out the expanded responsibility for ensuring quality health care assigned to us in recent legislation, and especially the Omnibus Budget Reconciliation Act of 1987. Increased funds are needed to:

- implement improved and expanded survey and enforcement activities in home health agencies and skilled nursing facilities ($14.4 million);

- survey and certify physician office laboratories that conduct more than 5,000 tests annually ($5.0 million);

- survey new Medicare providers ($3.3 million);

- increase coverage of participating laboratories to 100 percent from 60 percent ($2.9 million);

- provide cost of living raises for state surveyors ($2.4 million).

We believe that the significant increase in state survey and certification funding that we seek is consistent with the increased emphasis on health care quality evidenced in

recent congressional actions. Ensuring quality of care continues to be one of the highest priorities of my agency and this Administration.

Administrative Costs

HCFA's FY 1990 budget request for administrative costs is $329.4 million, a 4.1 percent increase over the comparable FY 1989 spending level. This amount, which represents 0.2 percent of HCFA's total outlays, is needed to support HCFA's workforce (personnel compensation, rent, postage, telephone, travel, supplies, training); to continue our efforts to upgrade information systems management; and to fund contracts that are essential for program reviews and analyses. Of the amount requested, $62.0 million would fund catastrophic health insurance implementation, with emphasis on the outpatient prescription drug program, which becomes effective in January 1991. Clearly, implementation of the drug program represents the biggest administrative challenge HCFA has ever faced.

The administrative cost request would support a staffing level of 4,017 full-time-equivalent positions, including 125 positions earmarked for catastrophic implementation. This would stabilize HCFA's workforce at the FY 1989 level -- a modest request given the range of new tasks required by recent legislative changes.

Conclusion

We in the Health Care Financing Administration are confronted with the need to maintain and improve administration of the current Medicare and Medicaid programs while we also proceed to set up the new catastrophic health insurance program -- the most sweeping change in Medicare law since the program's enactment in 1965. During the coming fiscal year, a wholly new payment process involving point-of-sale adjudication of prescription drug claims must be designed and put in place, linking Medicare with thousands of pharmacies all across the country. When operational, this system is expected to process more than 700 million claims per year, which will more than double claims volume.

In addition, further legislative change is on the horizon. The Administration has proposed a number of significant changes in Medicare and Medicaid and Congressional interest in these programs is as intense as ever. The need to bring the Federal deficit under control conflicts sharply with double-digit growth in health care spending. Continuing concern about equity in payment rates as well as other issues may stimulate changes in Medicare law.

Given our continuing responsibilities as well as the new demands that we must meet, we present our FY 1990 budget request as the minimum amount of resources needed to carry out our statutory mission. Through careful and cost-conscious management, we plan to live within our means and thus contribute to the reduction of the Federal deficit. I would be happy to respond to any questions you may have.

BIOGRAPHY OF LOUIS HAYS

Louis B. Hays is the Acting Administrator of the Health Care Financing Administration as well as the Associate Administrator for Operations (AAO). In his AAO position, he is responsible for overseeing the Bureau of Program Operations, the Bureau of Quality Control, the Health Standards and Quality Bureau and the 10 HCFA Regional Offices. These organizations account for 2,240 of HCFA's 4,000 employees nationwide. Their functions include certifying health care facilities for participation in Medicare and Medicaid through State survey agencies; reviewing the quality of care in Medicare through State survey agencies; reviewing the quality of care in Medicare through the Peer Review Organizations; funding the State Medicaid programs and overseeing the use of those funds; and processing and paying over 455 million Medicare claims through the Medicare fiscal intermediaries and carriers. In FY 1988 Mr. Hays, through the oversight of these agents, was responsible for ensuring the timely and correct payment of $118 billion in Medicare and Medicaid benefits at an administrative cost of $3 billion.

In addition, Mr. Hays has been given responsibility for implementation of the Medicare Catastrophic Coverage Act, the largest expansion of the Medicare program in its 23 year history. Mr. Hays also serves as the Co-Chairman of the Department of Health and Human Services' Catastrophic Coordination Committee, through which he is helping ensure successful completion of government-wide implementation activities.

Prior to joining the Health Care Financing Administration, Mr. Hays spent 2 years at the White House as deputy to the Assistant to the President for Policy Development. Mr. Hays previously worked for the Associate Director for Management at the Office of Management and Budget. Prior to that he was Associate Commissioner of Social Security for Hearings and Appeals.

From 1975 to 1981 Mr. Hays established and directed the Office of Child Support Enforcement, now a component of the Family Support Administration in the U.S. Department of Health and Human Services.

Mr. Hays joined the Federal government in 1973, serving for 2 years as senior legal advisor to the Administrator of the Social and Rehabilitation Service in HEW.

A native of California, he served as counsel to the County Welfare Director of Los Angeles County from 1969 to 1973.

Mr. Hays is a graduate of the University of Redlands, Redlands, California, and the School of Law of the University of California, Los Angeles.

Mr. Hays, 43, lives with his wife Maude and their sons Bret and Craig in Severna Park, Maryland.

OVERVIEW OF FISCAL YEAR 1990 REQUEST

Mr. HAYS. Thank you, Mr. Chairman. I might point out, Mr. Chairman, that I am pleased to be here in my capacity as the Acting Administrator of the Health Care Financing Administration to present HCFA's proposed fiscal year 1990 budget.

With respect to the Medicaid Program, the budget proposal is for $37.6 billion for the Federal share of benefits and administration of Medicaid in fiscal year 1990, a $3.3 billion or almost 10-percent increase above our current outlay estimate for fiscal year 1989. Our proposed law estimate for Medicaid is the same, since the costs of our proposals to improve benefits would be offset by the savings associated with our proposal to reform administrative costs matching rates.

With respect to payments to the health care trust funds, our fiscal year 1990 request for this account is $36.3 billion, a $5.1 billion or 16.4-percent increase over the fiscal year 1989 amount. These figures do not reflect our two legislative proposals: first, to extend the provision under which the premium for part B is set at 25 percent of aged program costs, which would save $617 million in fiscal year 1990 and; second, to extend the current carrierwide limitations on payments for clinical laboratory services, which would save $190 million. The increase in the Federal contribution to part B of Medicare reflects the rapid growth in part B program costs.

Turning to the program management area, we are requesting $37 million to fund research, demonstrations and evaluation activities in fiscal year 1990, an almost 27-percent decrease in the amount appropriated for these activities in the current fiscal year.

With respect to the Medicare contractor budget, the administration's fiscal year 1990 budget includes $1.4 billion for the Medicare contractor activity plus a $100 million contingency reserve. This amount requested is only $77.4 million above the fiscal year 1989 appropriation.

Without question, this modest increase in contractor funding has required some very hard choices. As my predecessor, Terry Coleman, explained before you in February, our priority had to be to provide adequate funding for the basic functions of processing Medicare claims and handling beneficiary inquiries and appeals. As a result, we were forced to reduce spending for the so-called payment safeguard activities. In a less constrained budget environment, we would have maintained and probably even expanded medical review, provider audit and Medicare secondary payer activities because they have been demonstrated to be cost-effective.

Turning to State survey and certification, this program ensures that facilities participating in Medicare and Medicaid meet certain quality and safety standards. We are requesting a total of $174.3 million for this activity, broken out between Medicaid and Medicare. Our budget calls for a $31.7 million or 47-percent increase in Medicare State survey and certification activities, primarily to carry out expanded responsibilities given to us by the Congress to continue to ensure quality health care. We believe that this significant increase is consistent with the increased emphasis on quality of care. I want to assure the subcommittee that ensuring quality of

care continues to be one of the highest priorities of our agency and the administration.

Turning, finally, to administrative costs, our fiscal year 1990 budget request for this activity is $329.4 million, a 4.1-percent increase over the comparable fiscal year 1989 spending level. This amount, which represents 0.2 percent of HCFA's total outlays, is needed to support our work force, to continue our efforts to upgrade information systems processing, and to fund essential contracts. Of the amount requested, $62 million would fund the implementation of the Catastrophic Health Insurance Program, with particular emphasis on the Outpatient Prescription Drug Program, a major challenge for the Health Care Financing Administration.

This amount would support a staffing level of 4,017 full-time-equivalent positions, including 125 which are earmarked for catastrophic health insurance implementation. This would stabilize HCFA's work force at the fiscal year 1989 level, we think a modest request given the range of new tasks required by recent legislative changes.

CONCLUSION

In conclusion, Mr. Chairman, we must maintain and improve, if possible, the administration of the ongoing Medicare and Medicaid Programs while at the same time we must implement the new Catastrophic Health Insurance Program, catastrophic being the single biggest expansion of the Medicare Program since its inception. We see further legislative changes on the horizon. Given our continuing responsibilities as well as the additional demands that are being imposed upon us, we believe that our fiscal year 1990 budget request represents the minimum amount of resources needed to carry out our statutory mission.

With that, Mr. Chairman, I would be pleased to respond to any questions that you may have.

REDUCTION IN PAYMENT SAFEGUARD SPENDING

Senator HARKIN. Thank you very much for that fine summary.

You said in your written testimony that for every dollar spent on payment safeguards, benefit outlays are reduced by $7 to $21.

Mr. HAYS. Yes, sir.

Senator HARKIN. Yet you are cutting that program.

Mr. HAYS. That will be a consequence of the fiscal year 1990 budget request, yes.

Senator HARKIN. You do not feel that we have reached the point of diminishing returns on this thing?

Mr. HAYS. No; certainly not. The reason for our reduction is not that, but rather, the result of the hard choices that I believe you reviewed with our agency at a hearing a couple of months ago. As we said at that time, we had really no choice but to protect the basic functions that the contractors carry out in the process of paying Medicare bills. And in order to do that we had to cut back on payment safeguard activities.

Senator HARKIN. There was no other place you could tighten up? How much money are we talking about now for the payment safeguard programs, $230 million?

Mr. HAYS. Our fundamental responsibility, as you know, Mr. Chairman, is to handle almost 500 million claims per year that come in from beneficiaries and providers and to take appropriate action on those, as well as to handle beneficiary and provider inquiries and appeals.

Senator HARKIN. Would you say it is part of that primary responsibility to make sure that the claims are accurate, that they are valid?

Mr. HAYS. Absolutely. I don't want to imply that we are totally eliminating that. We are not.

Senator HARKIN. What about once they are cut? It is a big cut.

Mr. HAYS. We are reducing it. In a perfect world, without budget concerns, without a deficit problem, we would undoubtedly not be making such a reduction. We would probably be proposing an increase.

Senator HARKIN. You want to cut the deficit. You want to cut wasteful spending. You are getting a return. If we have reached the point of diminishing returns, I could not agree with you more, but according to GAO and the inspector general, we are saving through this activity.

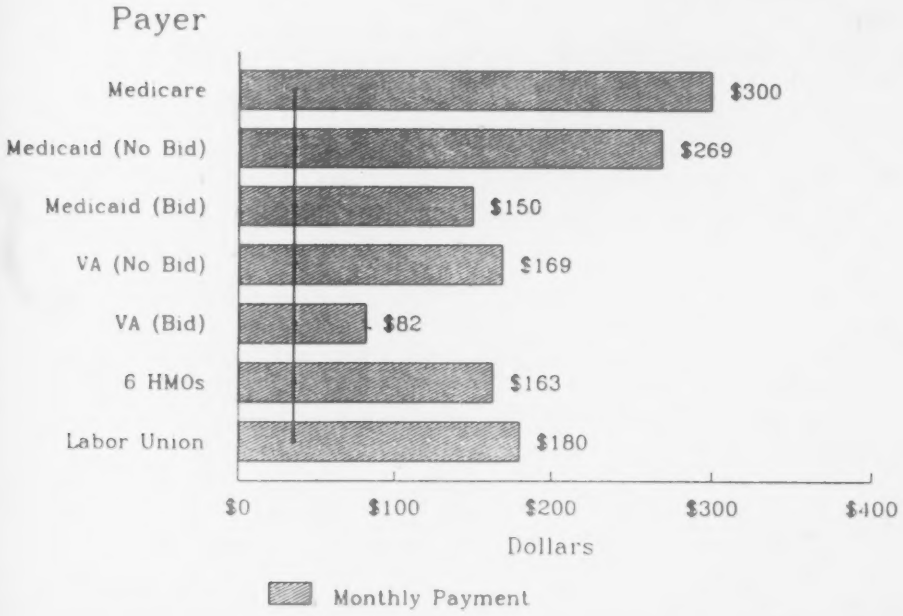
Mr. HAYS. There is a further complication, Mr. Chairman, in that while the savings from these activities are well documented, because of the way in which the budget is scored both by the actuaries in our Department and the actuaries or others in the Congressional Budget Office, the savings from these activities do not get scored in the budget, so it is a difficult problem for us.

MEDICARE PAYMENT FOR OXYGEN CONCENTRATORS

Senator HARKIN. I understand that. Let me turn to this chart up here. The inspector general's report has examples of the same company supplying identical oxygen concentrators to the Veterans Administration and Medicare in the same geographic area.

OXYGEN CONCENTRATORS

Typical Monthly Reimbursement



Under the VA competitive bid process, a supplier was paid $82 per month for rental while Medicare paid $300 per month rental. To quote the inspector general's report:

> Medicare's payments for the rental of oxygen equipment were typically two to four times the amount paid by the VA hospitals using competitive bid contract procedures.

The report went on to state:

> Almost all VA hospitals using competitive bid contracts for oxygen services were complementary of the quality of products and degree of maintenance and other services rendered by the contracts.

As you can see from the chart, Medicare at no bid was $269, VA with no bid was $169, and Medicare with a bid was $150. In every case it is considerably lower, in most cases almost 50 percent lower.

I understand that you have suggested a 5-percent cut in this area, is that right?

Mr. HAYS. We do have such a legislative proposal and we certainly support the point that you are making, Mr. Chairman. In fact, I appreciate you highlighting this problem that we are facing in the Medicare Program. We could not agree more with the point that you are making. The problem, though, is that, first of all, we are required by statute to pay for oxygen and other so-called durable medical equipment according to a new fee schedule approach and; second, we lack the authority to use the competitive bid approach that the Veterans Administration apparently does use. And our

use of a competitive bidding approach for oxygen and other items has been prohibited by the Congress.

Senator HARKIN. You are saying legislatively you are prohibited from competitively bidding this?

Mr. HAYS. That is correct. We have attempted to obtain the authority to test the competitive bidding process for oxygen and other supplies in the Medicare Program, and we have been unsuccessful, so we would welcome your support and assistance to get us this authority.

Senator HARKIN. We will see what we can do about that. Even without bidding, VA no bid is $169.

OXYGEN REIMBURSEMENT FEE SCHEDULE

Mr. HAYS. That gets back to the other part of the story where we are required by law to use a fee schedule. There have been some substantial restrictions placed upon our authority to pay at the lower more reasonable price. Our hands are very tied on this subject.

Senator HARKIN. I am looking at the IG's report. In the same geographic area, the same company, identical oxygen concentrators, VA paid $78 and Medicare paid $300. We are talking about the same company, same equipment, same area. I mean, that is unconscionable.

Mr. HAYS. You are absolutely right.

Senator HARKIN. You are saying you could not do anything about that? You could not say, hey, look, give us the same deal as VA?

Mr. HAYS. The bottom line, that is correct.

Senator HARKIN. What if they said it was $400, would you have paid that, $500, $600, $800?

Mr. HAYS. No; I wouldn't think that we would have to pay more than the $300, but the $300 is based upon what has historically been paid in the Medicare Program. And because of the way the law currently works, that is essentially what we are locked into continuing.

Senator HARKIN. Is that an upper limit, you can't pay any more than $300 or what? I am trying to figure out where the $300 comes from.

Mr. HAYS. I would be pleased to provide for the record a more detailed description of how it is and why it is that we end up with this result and why it is we are essentially prevented under current law from solving this problem that we absolutely agree exists.

[The information follows:]

RESTRICTIONS ON OXYGEN CONCENTRATORS

Section 4062 of OBRA 1987 requires payment for the home use of oxygen on the basis of fee schedules without regard to the type of oxygen delivery system, that is, gas, liquid, or concentrator. Section 4062, in establishing 1834(a)(10)(B) of the Social Security Act, further prohibits any adjustments for inherent reasonableness until January 1 1991. Also, section 4062(c)(2) prohibits the Secretary from conducting any demonstration project respecting alternative methods of payment for medical equipment.

Senator HARKIN. I intend to get to the bottom of this. That just does not make sense to me.

The inspector general says a savings of $200 million a year. There is our money for the Payment Safeguard Program right there.

Mr. HAYS. Absolutely.

Senator HARKIN. That would save us even more money.

Mr. HAYS. That is why we would love to use competitive bidding.

Senator HARKIN. I understand that, hopefully we can get that done this year. But, even without competitive bidding, I see us paying a lot less than that.

Mr. HAYS. The Omnibus Budget Reconciliation Act of 1987, OBRA 1987, specifically establishes the way for us to pay for oxygen. And essentially that law ties back into what the carriers have historically paid for oxygen and other supplies in the Medicare Program. We are specifically locked in by that statutory provision. And even though we would admit that many carriers in the past have paid too much for these supplies, nonetheless the law in effect grandfathers that history into the way in which we must currently pay for oxygen and other supplies.

Senator HARKIN. The inspector general's report notes that you, I guess I should say HCFA, issued voluntary guidelines to Medicare contractors in March 1987 which, if fully implemented, could save over $100 million a year. That is on the oxygen part. Yet the contractors are not eager to create local charge levels, believing equipment issues should be dealt with nationally. In view of this reluctance to voluntarily carry out your 1987 guidelines, why don't you just propose a nationwide payment limitation for oxygen concentrators?

Mr. HAYS. It is my understanding, Mr. Chairman, that the statute we are discussing specifically precludes us from doing that.

STATUTORY PROHIBITION ON COMPETITIVE BIDDING

Senator HARKIN. Have you proposed the law changes?

Mr. HAYS. I know that we have previously proposed authority for competitive bidding. I am not, frankly, sure whether we have yet proposed a change in this particular statute. I must point out, however, Mr. Chairman, that the statute closely reflects the views of the industry that is involved in this product and it had rather broad-based support in the Congress. Therefore, there was probably some thought on our part that the likelihood of substantially modifying the statute, that was just enacted by Congress so soon thereafter, was nil.

Senator HARKIN. Mr. Hays, I do not think it had broad-based support in Congress. I do not think anybody really understood it. That is how these things get through. I think we should find the bolts here to tighten this down. When you say the law wouldn't allow this, you are talking again about the budget reconciliation issue?

Mr. HAYS. I am referring to OBRA 1987.

Senator HARKIN. Could you supply to us the specific part of that law?

Mr. HAYS. We will be pleased to spell out exactly what our limitations are on the subject.

[The information follows:]

AUTHORITY FOR COMPETITIVE BIDDING

Legislation would be needed to amend section 1834(a) of the Social Security Act to permit payment for durable medical equipment, prostetics, and orthotics on a competitive bidding basis. The relevant sections of the Social Security Act (portions of sections 1833 and 1842) would have to be changed to permit competitive bidding for ambulance, laboratory, and other part B services. However, HCFA is not prepared at this time to seek legislative authority for competitive bidding for these services. At a minimum, we would need to gain experience from demonstrations prior to seeking such authority. In that regard, HCFA can take no actions when moratoriums are placed on our demonstration experiments (sections 4062(c)(2) and 4085(c) of OBRA 1987).

Senator HARKIN. Again, I do not understand, I don't mean to beat a dead horse here, but a 5-percent cut, you proposed a 5-percent cut in this area to save you money. That still does not do much. That brings it down from $300 to $285.

All of the rest of my questions have to do with competitive bidding, but if you say the law won't allow it, then I guess we will have to change that.

Mr. HAYS. That's right.

Senator HARKIN. Could you subcontract with the Veterans Administration to supply oxygen?

Mr. HAYS. We would be pleased to review that, but I doubt it.

Senator HARKIN. You could even give them a cut on the side and still make out, and help them out a little bit.

Mr. HAYS. With respect to competitive bidding, I know you are interested in that and several other areas as well, and, again, we are also interested.

MEDICARE PAYMENT FOR AMBULANCE SERVICES

Senator HARKIN. We will see what we can do. I would encourage you, in fact on the record I would ask you, to supply our subcommittee with more information in this area and in other areas in which you think we need to get this law changed to provide for competitive bidding.

Ambulance costs. Last month I held an oversight hearing, which we referred to earlier, which consisted of testimony from several Medicare contractors. The representative from South Carolina's Blue Cross/Blue Shield organization told of how helicopters were frequently used for nonemergency transfers of patients between hospitals, costing three times more than routine ambulance services.

Inspector General Kusserow estimates savings of $109 million could be achieved by limiting excessive charges even from ground ambulance services.

To illustrate the potential savings he cites examples such as the case where Medicare pays an ambulance company $106 per trip from a hospital to a diagnostic center, even though the same hospital pays only $55 for the same trip for non-Medicare patients.

Are you aware of these things?

Mr. HAYS. I am not aware of that specific example or that specific report.

Senator HARKIN. Mr. Kusserow identified one Medicare contractor that is already achieving savings of 15.8 percent using existing administrative authority. In a sample of six States the inspector

general found that the Veterans Administration is obtaining rates averaging 25 percent lower than Medicare payment rates without adversely affecting the quality of ambulance services.

What actions have you taken in response to the inspector general's recommendations to curb ambulance costs, or what plans do you have?

Mr. HAYS. First, I believe, Mr. Chairman, that the biggest part of that recommendation is the reference again to the Veterans Administration. It involves again the issue of competitive bidding.

Senator HARKIN. And you are not allowed to do that under ambulance services?

Mr. HAYS. That is the way the Veterans Administration has achieved those savings. It is my understanding, and I must admit to being not previously fully familiar with this subject, that, as with oxygen concentrators, we do not currently have the authority to use competitive bidding for ambulance services. Therefore, our reply would be the same, that we simply do not have the authority to do that currently. There has been some concern expressed within the agency about whether emergency services are something that should be obtained through a bidding process because of the importance of access to emergency services. I personally would be inclined to think that equal access could be assured but, be that as it may, the bottom line is, as I understand it, we do not have the authority to use competitive bidding for ambulance services.

Senator HARKIN. Why not require Medicare contractors to use their existing, I guess the phrase is "inherent reasonableness," authority to limit ambulance charges?

Mr. HAYS. Inherent reasonableness is a somewhat cumbersome procedure used by each carrier. I am advised that we have certain limitations currently on our ability to use inherent reasonableness. With respect to our specific ability to use inherent reasonableness to reduce ambulance costs, I would like to submit a response for the record to make sure that I am giving you the most accurate information.

[The information follows:]

INHERENT REASONABLENESS OF AMBULANCE RATES

Inherent reasonableness authority can be used to either lower or raise ambulance rates. In practical terms, however, we do not believe it would result in significantly lower ambulance rates than those currently imposed by the inflation-indexed charge [IIC]. The IIC was introduced as a reasonable charge factor in October 1985 and froze ambulance rates at the levels in effect in September 1985. (It bears noting that those rates were based on suppliers' 1983 charges.) Rate increases, which are limited to the Consumer Price Index, have been allowed only in 1987 and 1989. As a result of this change, the workload associated with inherent reasonableness has been exclusively compromised of requests requesting relief from grossly deficient rates.

Section 4062 of OBRA 1987 prohibits the Secretary from using inherent reasonableness authority to obtain lower rates for all types of durable medical equipment, including oxygen equipment, and prosthetic and orthotic devices until January 1, 1991.

Senator HARKIN. Again, you are going to respond to us on seeking legislative authority for some changes. You ought to include ambulance reimbursement rates.

I have a couple of other examples here just to point out how widespread this is. The inspector general pointed out that in a major Southwestern city a private company transports patients be-

tween a hospital and a local testing center for $35 each way. When that patient is discharged to home or nursing home the supplier charges Medicare $110.

A company in a west coast city contracts with a hospital and an HMO for $64.50 per trip. Medicare allows $90 for the same trip.

So, again, this is very widespread. When you tell me that you have got budget constraints, that you have got to cut down on payment safeguards, we have already got money right here to take care of it, if you have the necessary authority.

Mr. HAYS. That may be true if there is a way of using the result of the savings from program outlays to increase outlays for program management, which is perhaps a problem.

STANDARDIZED COMPUTER SYSTEMS

Senator HARKIN. I know, but we may be able to work that out, too.

Let's talk about the computer work. This came up also. For many years you funded more than 60 contractors to process claims under the Medicare Programs. I understand there is considerable duplication and overlapping in computer systems, even though Medicare contractors have been encouraged to voluntary share both hardware and software in order to cut the costs.

For example, I understand that 22 part A contractors share software, but this involves five different systems. On the part B side, 14 contractors share the cost of five different systems. So, while this is a start, there is still much that could be done to avoid having numerous contractors duplicate the expense of developing new software systems every time Congress changes the Medicare laws.

It seems to be occurring rather frequently these days. Significant economies of scale also remain to be achieved by sharing computer hardware. I understand that you have estimated $15 million could be saved the first year and $102.6 million over 3 years by requiring the larger two-thirds of Medicare contractors to share computer processing and maintenance cost.

Could you briefly describe to us how this proposal could work or would work?

Mr. HAYS. Yes; first, Mr. Chairman, your premises are essentially correct. We have a large number of Medicare contractors, currently almost 90. Historically, most of those contractors have developed their own computer systems. And every time that the law changes, that requires making all of those separate changes, which is very costly. As a result of that concern and those costs, we have become more aggressive in trying to get contractors to use standard systems or, at the very least, to use what we call shared processing arrangements or shared maintenance arrangements.

We have had some success in that and it clearly will result in savings. The problem is that our authority to, in the final analysis, mandate either the use of standard systems or these shared arrangements is somewhat limited. Our principal leverage is through persuasion and hard bargaining, so to speak. While we feel this is absolutely the right way to go and will produce the kinds of sav-

ings that you mentioned, there is some practical limit on our authority to accomplish that fully.

AUTHORITY TO REQUIRE STANDARD SYSTEMS

Senator HARKIN. What limit do you have on this authority? Surely we are not talking about competitive bidding here.

Mr. HAYS. No; but we are ultimately talking about our authority under the contracts that we have with the Medicare contractors to specifically require contractors to enter into these arrangements and to use standard systems.

Senator HARKIN. I just do not understand that. There is no legislative prohibition. You said it has to do with contractual arrangements that you have made. How long are those contracts good for?

Mr. HAYS. Well, essentially 1-year contracts.

Senator HARKIN. It seems to me these contracts roll up every time. You just go in and you say we are going to change this contract. This is our new position on it.

Mr. HAYS. We are, in our process of negotiating with the contractors, trying to move in this direction, but these are not legal mandates where we can merely by fiat tell the contractors what to do. In some of these areas they have to be willing to agree. These are contracts. The contractors are not statutory agents of ours.

Senator HARKIN. But they want those contracts. I have not met a contractor yet that did not want the contract.

Mr. HAYS. That is correct.

Senator HARKIN. They want it very badly.

Mr. HAYS. That is correct.

Senator HARKIN. Well, it would seem to me if they want the contract, then you say, look, what we are going to do is cut some costs. We are going to combine contractors to share hardware, share software, that kind of thing. I told you that 22 already share software on five different systems in part A, and in part B 14 share five different systems.

It is already being done out there, but that is just a small part of it. You said that you could save $102.6 million over 3 years just by requiring two-thirds of the contractors to share the processing and maintenance. You say there are 90 contractors?

Mr. HAYS. There are about 86 separate contractors.

Senator HARKIN. Again, that is a considerable savings. I have a hard time understanding why, since they want those contracts, you can't say, OK, if you want the contracts, here is what you have got to do, this is our side; you have got to share and combine with other contractors to cut the cost. I do not understand why they wouldn't want to do that unless they had some fixed overhead or something like that.

Mr. HAYS. As I said, we are moving much more aggressively. We have specifically, for example, told the contractors that we will not provide funding for any changes or enhancements to their computer systems that they would like to make unless they have agreed to enter into one of these shared arrangements. But in terms of our pure ability to say you must, in order to continue in this program, either adopt a standard system or enter into a shared arrangement, the bottom line is we do not have the full ability to make

this happen overnight. We are moving in that direction. We are making progress. We probably need a little bit of additional help and support in going all of the way.

Senator HARKIN. From whom?

Mr. HAYS. From the Congress.

Senator HARKIN. But there is no legislative prohibition.

Mr. HAYS. Contractors might suggest that there is also no legislative authority to go all of the way.

Senator HARKIN. You have the authority. We are doing a circular argument here now. You have that authority to go ahead and mandate something like this be done.

Mr. HAYS. That is at best difficult, extremely difficult to do from the practical standpoint of dealing with 86 contractors.

STATUTORY LIMITS ON CONTRACTING AUTHORITY

Senator HARKIN. I do not pretend to understand all of the details of how you operate. That is not my job. That is your job to understand the details. But I have got to understand why it is that you cannot do this. I am having a hard time understanding that.

Mr. HAYS. This is further aggravated by the fact that because of the way the contractor program is set up in the Social Security Act, our ability to enter into contracts of the nature that we think would be most beneficial to the program, our authority to take appropriate corrective action against contractors, our authority to replace contractors that are not performing well, is somewhat limited. Therefore, we have proposed a number of legislative changes to beef up our ability to manage effectively the Medicare Contractor Program and to give us more authority to have the kinds of contracts that we think would work best for the Government, would enhance our authority to control this sort of thing. We have made a number of legislative proposals that would beef up our ability to have effective, efficient Medicare contracts.

Senator HARKIN. Well, whatever you suggest legislatively, I am more than willing to look at and work on. Suppose we have a Medicare contractor. You go to them and say, well, we now want you to combine with these three or four other contractors to share computer software and maintenance. The contractor says, well, I really do not want to do that. We have our own system. We want to use our system. You come back and say, well, you have got to do this. They say, well, we won't. I suppose your position then is, well, for us to go out and find a new contractor may require more money, time and effort than it would be to just say, all right, go ahead and do it.

Mr. HAYS. Not only that, Mr. Chairman, but I think under our existing authorities, that in and of itself would not be a legal basis for, in fact, terminating a Medicare contractor. We just do not have that kind of unfettered authority.

Senator HARKIN. You do have the authority to propose certain aspects of the contract. It is a contract. You require them to do certain things. And it would seem to me that when a contract comes up for renewal, that you would come with your proposal to do this.

Let me rephrase the question. If there is a Medicare contractor up for renewal next month, this month, later this month, next

month, and there is, well, all of them will be up this year, right? I do not know how often they roll around. Is there a specific time when the contracts are up?

Mr. HAYS. For the most part, with a few exceptions, these are contracts that run on a fiscal year basis.

Senator HARKIN. So all of them are up September 30?

Mr. HAYS. And essentially they automatically renew. Mr. Chairman, I have with me this morning the person who is directly responsible for managing the Medicare contractors, Barbara Gagel, the Director of our Bureau of Program Operations. I think, given her greater detailed level of knowledge, she might be able to shed some additional light on the question that you are raising. And with your permission I would ask that she address some of these points.

STATUS OF CURRENT STANDARDIZATION EFFORTS

Ms. GAGEL. I am Barbara Gagel, Director of the Bureau of Program Operations for the Health Care Financing Administration. At the moment we are required under the Social Security Act to enter into cost contracts. Several years ago there was a provision added to the law that limited Medicare payment for program management functions to efficient services. That is the extent of the definition. Under that new authority of efficient services now we are, therefore, telling the contractors that indeed we do want them to share systems with one another and that we do, to the extent possible, want them also to share computer hardware. We have an aggressive program underway that started about 6 months ago to bring that about on a voluntary basis. It is voluntary in the sense that we are not forcing them to do it, but, if they refuse to do it, we are limiting the Medicare contract dollars that we make available to them for computer systems.

We would want to go farther than that because there is additional money to be saved by having more standardization. The primary problems with doing that are two. First, we do have to worry about Federal acquisition requirements, since the Medicare contractors are covered by Federal acquisition requirements in their subcontracts, and there are a lot of vendors out there who want the opportunity to bid on the various computer systems that the contractors have. And so we can't really direct them to go to one system but we have limited our financial support, if you will, to systems that can be shared. And we are taking a number of efforts to make sure the sharing takes place. The contractors generally are very supportive, after some thought, of that initiative with regard to sharing computer software.

Our second major problem is that contractors are very hesitant to join into arrangements where they share computer hardware with one another, although we do have some of that going on now on a voluntary basis and some others that we are actively encouraging to begin sharing. Their hesitance to do that relates, quite frankly, to the fact that they see that as a first step toward giving up their Medicare contract because they see that as a major function that they are losing. We are still working with them on that and we are, quite frankly, investigating whether or not we need

some changes in the wording of the law to allow us to direct that in a much more forceful way than we now have the opportunity to do.

Senator HARKIN. I understand they would be reluctant. But, I don't see why they would be reluctant because they thought it would be the first step toward giving up of their contract.

Ms. GAGEL. They see having that piece of hardware there as kind of like the meat and potatoes, if you will, of the contract. And they are aware that there has been a lot of talk in Medicare about moving toward regional processing, reducing the number of contractors. They would think the natural entities to end up being regional processors would be those contractors who have that hardware and who receive bills from others. And so by giving up something now, they are concerned that they may eventually be giving up the administration of the program altogether.

STATUS OF IOWA CONTRACTOR

Mr. HAYS. You may recall from personal experience that when we take some action against a Medicare contractor that threatens their continued participation in the program, that they react rather strongly to that and use the various means at their disposal to lobby against that sort of activity.

Senator HARKIN. Well, case in point. Very good. As I said, they want that contract. Not only do they lobby, but they shape up their system.

Mr. HAYS. We would hope so.

Senator HARKIN. Their error rate has gone down considerably. From everything I have seen they have shaped up their system, which is the deal that we made with Secretary Bowen.

Mr. HAYS. What I do not know, I do not know whether Barbara does know, is whether Iowa is taking advantage of systems efficiencies that we were talking about here today. They may well argue, yes, and that is a part of the point, they might argue do not talk to us about a new computer system to save you some money; only look at our bottom line performance. As you say, the performance is good, the error rate is down, et cetera, et cetera.

Senator HARKIN. I would not argue that at all. I would not even entertain that as a suggestion. They got their error rate down, and it shows that they were able to clean up their act, on the basis of the Nebraska contract. But that does not mean that they have reached the pinnacle of cost savings and efficiencies. We ought to force them to have those efficiencies.

Mr. HAYS. The next argument will be, well, if we give up this computer system and we enter into an arrangement with a contractor in another State, that is going to result in the loss of 10 jobs here and we do not want that to happen. I am just pointing out that what seems perfectly logical and is absolutely the right thing to do, in fact, in practice becomes very difficult and becomes a highly charged subject.

Senator HARKIN. It has been done in other areas. I just read you an example. It has been done in some areas.

Mr. HAYS. It is because we have been aggressive in trying to push them in that direction. And the more explicit authority that

we can get, the more successful we will be and the more money we will save.

Senator HARKIN. Do you know that Iowa has a shared system?

Ms. GAGEL. They are moving to one for their part A program. I think by the end of this fiscal year they will be on one for the part A program. We are looking at some plans they have now. They contract out their activity on the B side. And that contract is up for renewal sometime in 1990.

Senator HARKIN. Is that a shared contract with other contractors?

Ms. GAGEL. No; but under the request for Federal procurement that they will put out for the new system, it will be a shared maintenance system. That is where we are going to improve the RFP, and they have agreed to that.

Senator HARKIN. Here is a case in point where you have said that, for renewal purposes, your part B contract has to be a shared arrangement.

Ms. GAGEL. That is for the subcontract, yes.

Mr. HAYS. For the renewal of their subcontract for the system.

Senator HARKIN. That is fine. It is a shared contract. I don't care if it is a shared subcontract or a straight-on contract. It is the same thing, right? I mean, the subcontractor is doing other things.

Mr. HAYS. The point that I was making is that we have not threatened them with the loss of their overall Medicare contract.

Senator HARKIN. But you said you would not entertain the RFP unless it was that.

Ms. GAGEL. That is correct.

Senator HARKIN. What does that mean if you do not entertain the RFP?

Ms. GAGEL. They have to do a systems change. So in that particular instance, which does not apply in all contractor situations, that is clearly the case, yes. Their option, quite frankly, is and always has been that they can proceed to move forward maintaining that system without Federal support. And that is done to a certain extent. That is obviously a short-term as opposed to a long-term option for any contractor to pursue.

Senator HARKIN. It would still save us money.

Ms. GAGEL. Yes; it does, short-term.

UPCOMING CONTRACT NEGOTIATIONS

Senator HARKIN. I think we need to look into this even more. I gather there are proposals you have that we still have to pursue. I will not let go of this one. I will turn to your administrator. Your administrative ability, when those requests come up again in the fiscal year, should enable you to write that in your contract and put them on the line and see what they say. If you can get two-thirds of them sharing, it creates a savings.

Ms. GAGEL. I just happened to think of one thing I should mention for the record. We do have ongoing contracts with these organizations and the terms of those contracts are renewed every 2 years. We are going into contract negotiations this summer. And this is one provision that the Government is putting on the table, a

provision to add to these contracts. That will significantly strengthen our authority if we are able to negotiate that.

MEDICARE PAYMENT FOR LABORATORY SERVICES

Senator HARKIN. I am glad to hear it. Let me move on to lab fees for a second. Even though Medicare pays a major share of our Nation's health care costs, it does not necessarily pay prices that are comparable or at least as low as those paid by some physicians. In some cases, independent medical laboratories give deep discounts to some physicians. They claim that their cost of doing business with these physicians is much lower than their cost of doing business with Medicare.

In these situations the laboratory's testing charges to physicians are much lower than the charges allowed under fee schedules established by Medicare.

I understand that some laboratories charge Medicare significantly more than they charge private physicians for the same tests. Is this so, and to what extent is this practice occurring?

Mr. HAYS. We would generally concur with that assessment, Mr. Chairman. We probably on average are paying too much under Medicare for laboratory services. We are, as I understand it, required, in fact, by current law to go to a national fee schedule for paying for laboratory services which we believe will result in continued higher-than-necessary payments. Again this is a statutory requirement that we are faced with.

Senator HARKIN. This is a statutory requirement?

Mr. HAYS. Yes; that is correct. And we have specifically in the past proposed authority for other ways of paying, such as the competitive bids process that has been barred.

Senator HARKIN. Please send to us the provision that specifically relates to this point.

Mr. HAYS. Yes.

[The information follows:]

RESTRICTIONS ON LOWER LAB RATES

Clinical diagnostic laboratory tests performed in a physician's office, by an independent laboratory, or by a hospital laboratory for its outpatients are reimbursed on the basis of fee schedules. These fee schedule amounts were calculated according to a statutory formula.

Section 1833(a) and section 1833(h) of the Social Security Act present fee schedules as an exception to reasonable charge rules. Consequently, because fee schedules have a different basis from the reasonable charge rules, other authorities for the reasonable charge methodology such as comparability limits (that is, the rates allowed by carriers in their private businesses) and inherent reasonableness may not be used.

We also note that the administration's budget proposal contains a proposal to eliminate the national fee schedule which is effective January 1, 1990. The rationale for the elimination is that the provision as currently constructed would cause increases in the payment for clinical diagnostic laboratory tests. Current methodology for such tests limits payments to the median of all the fee schedules established for a particular test, that is, the national limitation amount. However, the proposed national fee schedule does not take into consideration the effect of the national limitation on payment and substantial increases in payment will result if the national fee schedule is implemented as presently drafted.

Senator HARKIN. So you have a set fee schedule and, even though it is more than they charge physicians, you can't pay any less than that?

Mr. HAYS. That is the bottom line of it, as I understand it, yes.

Senator HARKIN. The more I get into this the more I am just amazed. I am getting more and more amazed. How much money are we talking about in the labs? Do you have any idea?

Mr. HAYS. I am sure we have a figure. I do not know what it is.

Senator HARKIN. The IG's report of last November says that current Medicare fee schedules are about 170 percent higher than the actual amounts invoiced to physicians for the same tests. A savings amount has not been determined, but based on 170 percent differential noted at the one lab, the potential savings could be substantial. In 1986, Medicare payments for clinical lab tests were about $700 million.

Mr. HAYS. As a matter of fact, Mr. Chairman, I was reviewing just yesterday a report from the Inspector General's Office on the subject of paying for clinical laboratory services. I am not sure whether it is the same report that you are referring to. The only dispute between the Health Care Financing Administration and the Inspector General's Office was over the amount of money that we were overpaying. And we thought the amount that we were overpaying was higher than what the inspector general had estimated in their report. So that indicates the nature of the problem. In other words, we agree. The only dispute is how much we are paying is too much, and we are inclined to think that the amount we are paying is too much and even maybe higher than what the inspector general had estimated. I should point out that I understand that the General Accounting Office shares this view and has similarly reported.

CATASTROPHIC HEALTH INSURANCE PUBLIC INFORMATION

Senator HARKIN. Let me talk about catastrophic health insurance. A significant number of Iowans have expressed their concern about the way benefits under the recently enacted catastrophic health insurance legislation are to be financed. Yet a poll conducted by the American Association of Retired Persons shows that 65 percent of persons 65 and over support the new law, and only 21 percent oppose it. One of the problems seems to be a lot of misunderstanding about the costs and benefits of the Medicare catastrophic coverage.

Do you have any easy-to-understand conversion charts so people can see what they may expect to pay, based on their income, compared to the value of benefits? Furthermore, what are you doing to try to educate Medicare beneficiaries about this new law?

Mr. HAYS. If I could answer the second part of your question first, Mr. Chairman, we have done a lot and will continue to do more things to provide education and information to our Medicare beneficiaries. We started by putting out a brochure that explained the new catastrophic law which went to all 32 million Medicare beneficiaries.

Senator HARKIN. Do you have that brochure?

Mr. HAYS. I don't have it with me but I can certainly provide it. We updated the so-called Medicare Handbook, which is the description of all Medicare benefits, and it included the new catastrophic provisions. And for the first time in many years, perhaps the first time ever, since the beginning of the program, we actually sent the handbook to all 32 million beneficiaries, not just new people coming into the system.

We established a toll-free hot line, and some 10,000 people a month are taking advantage of this service. We have done public service announcements on radio and television. Our 10 regional offices have all been on a rather ambitious speaking engagement schedule to local community groups, senior citizen groups, explaining how catastrophic works and what the benefits are and the costs. I understand that the Internal Revenue Service has more specific information and some sort of pamphlet to explain how the income-based premium works.

In the future, as we bring the rest of the program on-line, January 1, 1990, January 1, 1991, we will continue to be updating the Medicare Handbook and will continue to send it to all current Medicare beneficiaries and will consider other appropriate steps, check stuffers and the like, to make sure that everybody is aware of what is going on.

I should add that we have also been working closely with senior citizens groups, such as AARP, to make sure that they, through their channels of communication, are also putting out the information about catastrophic.

In terms of the first part of your question about something that would very specifically show what Medicare beneficiaries are paying and how that is derived and then what they get in exchange for that, I doubt that we have in one place one document that specifically does what you are suggesting. It is certainly something that we could consider doing.

Senator HARKIN. A kind of a conversion chart or something, where if you know what your income is and what taxes you pay, you can determine how much more you are going to have to pay?

Mr. HAYS. I think the Internal Revenue Service has, in effect, done that with respect to calculating the income tax based portion of the premium, but we will be glad to review that and see if it does what you are suggesting.

[The information follows:]

COSTS/BENEFITS COMPARISON OF CATASTROPHIC

One of our top priorities in the implementation of the catastrophic provisions is to ensure that Medicare beneficiaries understand all aspects of these new and expanded benefits. Our efforts to increase beneficiary awareness have included mailings to all beneficiaries of a special catastrophic notice and a new Medicare Handbook. Each of these items describes the catastrophic benefits as well as the beneficiary's share of the costs.

As you know, with the unique financing of the catastrophic program, the specific premium amount paid by a beneficiary will depend on his or her income level. HCFA publications discuss in specific terms the catastrophic portion of the monthly SMI premium (stating, for example, the $4 per month is added to the basic premium of $27.90 in 1989). Presently, the supplemental premium is discussed in terms of a minimum and maximum premium amount since it is based entirely on an individuals's Federal tax liability. However, we will be able to move to a more detailed presentation of the supplemental premium amounts as soon as the Department of

the Treasury (IRS) completes its development of the official income distribution charts for use in filing tax returns. Until these official charts are released, we are encouraging beneficiaries with specific requests to contact the IRS.

I agree with you that a chart summarizing the catastrophic premiums would assist the beneficiaries in knowing just how much these new catastrophic benefits will cost them. Let me assure you that, as soon as detailed catastrophic premium information becomes available, HCFA will make every effort to communicate these facts (for example, from the Treasury tables) to all Medicare beneficiaries and will consider the development of an accurate and comprehensive Medicare premium chart.

Senator HARKIN. You have an 800 number that people can call about this, right?

Mr. HAYS. That is correct.

Senator HARKIN. My staff tells me it is busy all of the time.

Mr. HAYS. I understand that we are getting some 10,000 calls a month. However, I have not heard that we have had a problem of busy signals on this one.

IMPLEMENTATION OF DRUG BENEFIT

Senator HARKIN. One of the big things you are going to have is a drug benefits program.

Mr. HAYS. Absolutely. It is our biggest challenge.

Senator HARKIN. You mentioned that in your opening remarks that it starts in 1991?

Mr. HAYS. Well, the full implementation of outpatient prescription drugs occurs on January 1, 1991. Some people would say 1993 in the sense that that is when current law has the coinsurance go down to 20 percent; 50 percent is the way it starts out, but in our terms full implementation on January 1, 1991.

Senator HARKIN. The claims would still be the same?

Mr. HAYS. The system is supposed to be fully operational January 1, 1991.

Senator HARKIN. How much progress have you made so far in developing a new claims processing system to handle this?

Mr. HAYS. We have made good progress, Mr. Chairman. This is going to be a revolutionary approach to processing claims in the Medicare Program. Unlike the problems that we have been talking about previously on the systems costs for the regular Medicare contractors, we are going to have an entirely new system procured through different approaches. And instead of having 86 contractors processing drug claims, we are going to have 3, 4, or 5 contractors processing drug claims.

Senator HARKIN. On a regional basis?

Mr. HAYS. And instead of the current system where a person sends in a claim and waits for 1 month to get a response, the vast majority of these claims will be processed while the person is waiting at the counter of the drugstore. This will happen electronically, which will not only be faster, providing much better service for the beneficiary, it will also be much less costly. We think that it is going to cost us on average half as much to process a drug claim as what it currently costs us to process a regular claim in the Medicare Program because it will be so highly automated.

Senator HARKIN. How are you going to keep from having one area of the country pay very high payment rates and another part pay very low?

Mr. HAYS. In terms of how much Medicare will pay for the drug itself as opposed to how much we will pay for the cost of processing the claim, the statute spells out the payment methodology. Frankly, there has been some concern that the payment methodology that is spelled out in the statute for the actual drug costs themselves might be overly generous. It is perhaps a bit premature to say that because obviously the program hasn't begun and obviously the prices have, therefore, not yet been established. Nevertheless, the law is quite explicit as to how the Secretary is to go about establishing the payment methodology for paying for prescription drugs.

RURAL HOSPITAL PAYMENT

Senator HARKIN. I have a couple of questions on rural health care that I want to cover with you. In rural areas, the cornerstone of the health care system is the hospital. Without rural hospitals there is just no access to health care. Since 1980, over 200 rural community hospitals have closed and another 500 are on the verge of closing right now.

In order to respond to the rapid changes in health care needs, many rural hospitals should rethink their mission and restructure how they deliver services. How is the Department helping rural hospitals respond to the changes of the last few years and some of the changes yet to come? Are you proposing any steps to ensure health care for children and families who live in rural areas, and to the Medicare beneficiaries who live in rural areas?

Mr. HAYS. Mr. Chairman, we are currently reviewing, on a broad-scale basis, our policy toward rural hospitals. This is a particular interest of our new Secretary, Dr. Sullivan, and he has asked that we undertake a review of the entire rural hospital situation.

A couple of points. There have been some changes to the hospital payment system over the past 2 years that have resulted in higher payments to rural hospitals for Medicare than would otherwise have occurred without those changes. We also have some research underway to see whether there are different ways of paying rural hospitals without the potential disadvantage that rural hospitals have under the prospective payment system.

As you undoubtedly know, Mr. Chairman, for many hospitals, rural or nonrural, Medicare by itself is not the sole determining factor as to whether or not these hospitals are going to survive. There are many hospitals that are in such bad shape financially that making adjustments in the Medicare payment system is simply not going to make a difference. In fact, I was interested in a study that was recently announced in one of the health care journals that found that of all of the reasons why hospitals close, Medicare was, in fact, the least major cause of the closure. Low occupancy rates, bad management, poor quality, uncompensated care were found in this study to be more important than Medicare as to why these hospitals have closed.

Nonetheless, we are actively looking at the prospective payment system in order to see whether further changes should be made, particularly to protect access to care. We have, as you know, sole

community hospitals which are an example of a form of advantageous payments under the prospective payment system, and we are looking to see whether changes should be made to expand the number of sole community hospitals that qualify for enhanced funding.

Senator HARKIN. I really do not have any further questions. I will submit the rest of the questions for the record. We need to move ahead. Unless you have any HCFA questions in particular, I would like to move ahead to Dorcas Hardy and the Social Security Administration. Is that OK with you?

Senator COCHRAN. That is fine. If I could just make one comment?

Senator HARKIN. Yes; I recognize my colleague.

RURAL HEALTH INITIATIVES

Senator COCHRAN. Mr. Chairman, thank you very much. I wanted to just come by, and I am sure you covered this probably, if not in your opening comments or your written questions. We do have a continuing problem in States like Mississippi, Iowa, and I am sure others where small town hospitals, rural health care delivery systems, feel like they are being discriminated against by our reimbursement system.

Do you have any inkling that there is going to be an initiative from the administration to try to deal with this and equalize or make more similar the reimbursement schedules for those who live in the small towns or not in the large cities?

Mr. HAYS. In fact, Senator, we were just addressing that. To summarize two or three major points, over the past couple of years there have been changes made to the hospital payment system under Medicare to give rural hospitals a larger increase than they would have otherwise received.

Senator COCHRAN. What about physicians or procedures that are performed in small town settings, the reimbursement system?

Mr. HAYS. We do have some research and activities underway to look at physician services as well. However, most of this issue is generally focused around the problem of the hospital, the reimbursement of the hospitals as opposed to physicians. Physician payment is sort of another, somewhat separate but related issue.

Senator COCHRAN. It comes under your jurisdiction, though, you administer that?

Mr. HAYS. Yes; it does. And there are proposals to change the way in which physicians are paid under Medicare as well. For example, the Physician Payment Review Commission, which is a panel established by the Congress, is in the process of making recommendations to the Congress for changing the way in which physicians are paid. And one result of those recommendations would be, in general, higher payments for many physicians in rural areas.

Senator COCHRAN. Thank you, Mr. Chairman.

Senator HARKIN. Thank you. Before we bring up our next witnesses, do you have a few questions?

LOW-INCOME MEDICARE BENEFICIARIES

Senator BUMPERS. Yes; why would 4 million Medicare beneficiaries be eligible for Medicaid? How does that happen?

Mr. HAYS. You may be referring to the new provision under the Catastrophic Health Insurance Program.

Senator BUMPERS. Here is what my staff memo says, and you can argue with them if you want. They are low income Medicare beneficiaries.

Mr. HAYS. Under the Catastrophic Health Insurance Program, these individuals, low income Medicare beneficiaries, become eligible to have their costs of Medicare paid for by the State Medicaid Program. So-called qualified Medicare beneficiaries, who are low income Medicare beneficiaries, have their coinsurance premiums and deductibles paid for by the State through the Medicaid Program. That was a provision added by the Congress to the catastrophic legislation to provide further financial protection for low income Medicare beneficiaries.

MEDICAID ELIGIBILITY RULES

Senator BUMPERS. Mr. Hays, George Bush said in the State of the Union Address that he wanted $2 billion, I think he said this in the State of the Union Address, he wanted $2 billion more for Medicaid, is that correct or not?

Mr. HAYS. I am not familiar with the precise figure the President cited in that speech, but as I said in my opening statement, our fiscal year 1990 request for Medicaid benefits and administration is $3.3 billion higher than expected fiscal year 1989 spending.

Senator BUMPERS. You are asking for almost $3 billion more, but that includes, I assume that is mostly entitlement increases?

Mr. HAYS. The President has proposed in his budget several enhancements to the Medicaid Program to increase coverage for pregnant women and infants so that our problem of infant mortality can be more adequately addressed in this Medicaid Program. And that proposal, if enacted, would result in some quarter of a million additional pregnant women and infants being covered under the Medicaid Program.

Senator BUMPERS. Are the States still essentially the determiner of who is eligible for Medicaid within certain broad parameters that you all set out?

Mr. HAYS. Essentially, although I will say that there are an increasing number of mandatory provisions that the States must adopt.

Senator BUMPERS. Do you have a mandatory provision about how much income a family of four may have? For example, let's just take my State, for example, what if my State wanted to say if you make more than $3,500 a year for a family of four you are not eligible for Medicaid, could they do that?

Mr. HAYS. I think in general that is up to the State. However, are you are referring back again to Medicare beneficiaries?

Senator BUMPERS. No; forget about it. I am talking about the poorest of the poor.

Mr. HAYS. In general I believe that is correct. There are certain exceptions. For example, the President's budget proposals would

mandate Medicaid coverage for pregnant women and children up to 130 percent of the poverty line. That would remove the State's discretion for that particular category.

SIZE OF THE UNINSURED POPULATION

Senator BUMPERS. I strongly favor that. We have been moving. Our Government has been a leader in this field of trying to increase the coverage for pregnant women.

What would it cost, first of all, how many people in this country are below the poverty line but not eligible for Medicaid?

Mr. HAYS. I don't have the answer to that, Senator, but I would be pleased to check and provide it for the record.

[The information follows:]

BELOW POVERTY LEVEL MEDICAID INELIGIBILITY

According to the Census Bureau's Current Population Survey, approximately 20 million persons with prewelfare family incomes below the Federal poverty level were not covered by Medicaid in 1987. This represents about 5 percent of the population below poverty.

It should be noted, however, that Medicaid coverage for those below the Federal poverty level is inversely related to prewelfare income levels. For individuals with prewelfare incomes less than 25 percent of the Federal poverty level, 68 percent were covered by Medicaid. For individuals with prewelfare incomes between 75 and 100 percent of the Federal poverty level, only 19 percent were covered by Medicaid.

Senator BUMPERS. Do you have a guess?

Mr. HAYS. I am sorry, I don't.

Senator BUMPERS. It would be in the millions, though, wouldn't it? I mean, Medicaid obviously does not reach everybody that needs health care that has no coverage?

Mr. HAYS. That is correct.

Senator BUMPERS. For example, if you had a family of four and you were making, say, $9,000 and the poverty level is $13,000, obviously those people ought to be entitled to some assistance on health care. Maybe the guy is working, making $9,000 a year, and his wife is a homemaker, but he is not covered by Medicaid because of the State rule that says if you have over $7,000 in income you are not eligible.

Mr. HAYS. We have about 25 million people who are currently covered by Medicaid in this country. How many people there are above that who are defined as being——

Senator BUMPERS. I am talking about just people out there who are not covered by Medicare or any private coverage or anything else.

Mr. HAYS. That is an issue that certainly the President is aware of and the administration is going to be reviewing and probably coming forward with some sort of proposal. Dr. Sullivan our new Secretary, hopes to work as part of the administrationwide review of this question.

Senator BUMPERS. This thing about buying, the States buying into the Medicaid system, or maybe even allowing the private sector to buy into the Medicaid system, do you think that is a good idea?

Mr. HAYS. It is certainly an idea that is worth exploring.

Senator BUMPERS. You would agree with me that to have 37 million people in this country uninsured is really a travesty, is it not?

Mr. HAYS. Certainly it is difficult.

Senator BUMPERS. Do you think this is a partial solution to that, a good partial solution?

Mr. HAYS. The idea of buying in?

Senator BUMPERS. Yes.

Mr. HAYS. It is certainly an idea that the President discussed in the campaign and it is an idea that is being explored within the administration. And I hope it will bear some fruit.

RURAL VERSUS URBAN PAYMENT RATES

Senator BUMPERS. Mr. Chairman, I appreciate your indulging me on this, but I have been wanting to talk to this gentleman for some time.

You have already talked about rural hospitals. We had five close last year. We have 8 that probably will close this year, and 22 total, and we have about 80 so-called rural hospitals.

What basically is the differential between hospital reimbursement for urban and rural? I am talking about, you have got about three classifications, the super urban, the urban, and then the rural.

Mr. HAYS. There are currently three payment rates.

Senator BUMPERS. Just take the second urban rate. What is essentially the difference between, in percentages, the difference between the reimbursement rate between St. Vincent's in Little Rock, and Little Rock is just an urban, it is not like New York City?

Mr. HAYS. There is a substantial difference in payment rates. I am sorry, I don't have the precise figures at my fingertips. I would be pleased to provide them for the record, but clearly the PPS system does pay a higher rate to urban than rural facilities.

URBAN AND RURAL HOSPITAL DIFFERENTIAL PPS RATES

The differential between standardized PPS payment amounts for urban and rural hospitals, which was legislatively mandated to reflect the lower costs of rural hospitals relative to their urban counterparts, is now about 12 percent. This is the difference in PPS payment rates prior to adjustment for case mix, wage levels and indirect teaching costs. This differential had been as high as 23 percent, but has been reduced by recent measures such as differential outlier payments, case weighted payment rates, and differential updates for urban and rural hospitals.

Mr. HAYS. However, I would point out that for the last 2 years the Congress has established a higher update of the PPS payment for rural hospitals. This is something, again, something that Dr. Sullivan is very aggressive in and he has asked us to take a hard look at it. He is particularly concerned about the question of access to care.

Senator BUMPERS. I am just trying to say that the ones that can be viable but which are going under because of what I think is terribly discriminatory. I know what the cost in my State is, and I can tell you there is not that big a difference, not nearly as big a difference as HCFA makes in the reimbursement.

Mr. HAYS. As I say, we do not arbitrarily establish those rates. It is according to a fairly elaborate process that takes into account

real information about costs and other statutory requirements. We are particularly interested and concerned about so-called sole community hospitals which serve Medicare people or people who do not have other hospitals within a reasonable mileage from their home. We are looking to see whether there are additional things that we can do to make sure that there is access to the care through these sole community hospitals.

Senator BUMPERS. Mr. Hays, how quickly can you furnish me this differential that I have just asked you about, right away?

Mr. HAYS. It is readily available. I just do not happen to have it.

Senator BUMPERS. When you say you are concerned and so on about it, I mean, showing concern is one thing. Doing something about it is quite another.

Yesterday Senator Harkin, who sits on the Small Business Committee with me, we were having a confirmation hearing with Susan Ingall, to be head of the Small Business Administration, and I never heard as many eloquent statements about rural America. And everybody loves rural America, and I am a rural State, and everybody wants to do something about it until it comes to doing something about it.

Mr. HAYS. Senator, yesterday I met with Dr. Sullivan on this very issue. We are in the middle now of a process that we are required by law to go through, publishing in May, the proposed regulations for how we will pay hospitals starting October 1. And we are required to publish the final regulation in September setting that out. So this is not just rhetoric. We are actually in the middle of working on this right now.

REDUCING MEDICARE OUTLAYS

Senator BUMPERS. How are you going to achieve the $2 billion savings in Medicare that the budget negotiators are talking about right now? I mean, the President wanted $5½ billion. I think the negotiators reached $2 billion.

My question is, considering all of the problems with Medicare, how can you cut anything?

Mr. HAYS. I first point out for the record that the original budget of the President proposed a 10-percent increase in Medicare funding, and the so-called $5 billion cut is really the difference between 10 percent growth in Medicare and the 14-percent growth in Medicare that would occur in the absence of any legislative changes.

Senator BUMPERS. I didn't know that.

I appreciate that information.

Mr. HAYS. We are not talking about cutting $5 billion.

Senator BUMPERS. So when you talk about cutting $2 billion, you are talking about, say, the difference between, you say, 11 percent, 12 percent growth, and 14 percent.

Mr. HAYS. To cite one example of how a figure can be accomplished, we are proposing that the part B premium, the provision that says that 25 percent of the part B premium——

Senator BUMPERS. Comes from Medicare payments?

Mr. HAYS. If the requirement that the premium fund 25 percent of the program continues in law, then that will increase revenues to the Medicare Program substantially. We have other specific part

B savings proposals, physician savings proposals, that would not only save money for the Medicare Program in general but would indirectly save money for Medicare beneficiaries by avoiding what would otherwise be an even higher premium for them to pay.

Senator BUMPERS. Do you know with some reasonable degree of accuracy what it would cost to equalize urban and rural payments, what it would cost the Medicare system?

Mr. HAYS. Again, it is not a figure I have on the tip of my tongue.

Senator BUMPERS. A lot of money I am sure?

Mr. HAYS. Yes.

Senator BUMPERS. How long have you been at HCFA, Mr. Hays?

Mr. HAYS. I have been at HCFA for 3 years. I have been the Acting Administrator for the past month. Fully equalizing it may not be the way to go because I think you really need to worry about preserving access to care, concentrating on those facilities which are needed to provide access to care for beneficiaries. There are some hospitals that have such a low-occupancy rate, 10 to 20 percent, that we would really be throwing money down the drain.

MEDICARE BUDGET PROPOSALS

Senator BUMPERS. Incidentally, if you reduce Medicare by, say, even $2 billion, you are not going to be maintaining current services, are you; you are going to have to figure out some way to cut current services?

Mr. HAYS. We will be expanding services.

Senator BUMPERS. You are going to be serving more people, but I am talking about current services, what they are entitled to for a particular payment.

Mr. HAYS. For example, part of the budget proposes to reduce certain overpriced surgical procedures, so certain Medicare providers would receive the lower payments. We are not talking about increased cost for Medicare beneficiaries or cuts for Medicare beneficiaries.

Senator BUMPERS. One final question, Mr. Chairman. Do you know how much money we would collect if we required all people who make over $49,000 a year, is that the cutoff this year on Social Security, Mr. Chairman, $49,000?

Mr. HAYS. It is in that vicinity.

Senator BUMPERS. $47,000, $49,000, whatever, $48,000?

Senator HARKIN. Between $45,000 and $50,000.

Senator BUMPERS. If we made people like Tom Harkin pay the 1½-percent Medicare portion of his Social Security payment, if we made him pay that on the whole one-half million dollars he makes every year, how much money does that produce nationally?

Mr. HAYS. Again, Senator, we have the estimates, I am sure, of how much that would bring in.

[The information follows:]

EARNINGS SUBJECT TO PAYROLL TAX

If the cap were lifted, the additional income generated for a full year without the cap would be $8 billion.

Senator BUMPERS. Does anybody with you know? Does any of your staff know? Well, Social Security is next. They will talk about that one.

You see, I am all for that. I don't want Senator Harkin getting off too light.

Senator HARKIN. Removing the cap?

Senator BUMPERS. Yes; I think it will produce a lot of money and I think we can use that money to save a lot of rural hospitals. They can't all be saved. I recognize what you are saying.

Mr. HAYS. We did have proposals in the budget that would extend the Medicare premium at 25 percent of aged program costs and apply the payroll tax more broadly to all State and local employees. Those changes would also bring in a fair amount of additional revenue.

Senator BUMPERS. You can't talk about rural America and developing rural America and sit and literally cut the heart out of a community because a lot of them that is what you do when you let that hospital go under.

I know some administrators that are bright, hard working, dedicated people, and they still just cannot make it. Incidentally, that is not the only thing that is squawked about, but I won't burden the record with it now.

Thank you, Mr. Chairman.

Senator HARKIN. The other thing to get into with rural hospitals, while you are on this, is that a lot of times rural hospitals practice a more conservative form of medicine than do urban hospitals. They cut costs. They are more conservative in the way they do things. So, therefore, they get their reimbursement rate cut down even more, because urban hospitals can show, here, this is what their costs are. They are higher. The rural hospital's costs are even lower so they say, well, we will cut you even more. For them it is a bad situation. I am just wondering if HCFA has ever taken a look at rural hospitals and some of the cost-saving techniques that they use and apply those techniques to some of the urban hospitals? There might be something there.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Mr. Hays, thank you very much. I look forward to being able to look at the responses to the questions and the information we asked for. I appreciate it very much.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

REMOTE RURAL AREAS

In the Omnibus Budget Reconciliation Act of 1987, Congress responded to a disturbing trend whereby rural physicians were receiving a disproportionate number of adverse decisions by Peer Review Organizations. The 1987 legislation specifically stated that "the (PRO) shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and other appropriate factors...that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis."

Question. To what extent is HCFA prepared to ensure that this mandate from Congress is honored?

Answer. We believe that the PROs, based upon our earlier instructions, already take into account "social norms" when they make determinations.

We are in the process of identifying other types of cases that would be allowable under this provision. In doing this analysis, we have consulted with our Office of General Counsel and have sought input from the American Association of Retired Persons.

Once the types of situations are outlined, we will issue instructions to the PROs outlining what new actions need be taken.

Question. What steps has HCFA taken to monitor the efforts of PROs to take into account the realities of providing care in a rural setting?

Answer. HCFA monitors PRO performance through the Peer Review Organization Monitoring Protocol and Tracking System (PROMPTS). The PROMPTS used to evaluate PROs under the Second Scope of Work (SOW) included re-review of samples of PRO decisions by HCFA regional offices. The regional office staff performing the re-reviews were familiar with the unique nature of rural practice.

If problems are found, the PROs are requested to submit a corrective action plan. The results of the regional office's review are used in arriving at decisions on the renewal of PRO contracts.

REMOTE RURAL AREAS

Question. Will HCFA pursue a policy that promotes the use of rural practitioners when reviewing the cases of rural physicians?

Answer. We always encouraged PROs to use physician reviewers who practice in similar settings as the physician whose services are being reviewed.

In April, 1987 we issued a formal manual instruction requiring that PROs use physician reviewers who practice in rural settings to review care rendered in a rural setting.

The new PRO scope of work, which is effective April 1, 1989, also reinforces that this policy is an ongoing requirement.

CONSOLIDATION OF COMPUTER WORK

For many years, you have funded more than 60 contractors to process claims under the Medicare program. I understand there is considerable duplication and overlap in computer systems, even though Medicare contractors have been encouraged to voluntarily share both hardware and software, in order to cut costs. For example, I understand 22 Part A contractors share software, but this involves 5 different systems. On the Part B side, 14 contractors share the costs of 5 different systems. While this is a start, there is still much that could be done to avoid having numerous contractors duplicate the expense of developing new software systems every time Congress changes Medicare laws--which seems to be occurring rather frequently these days. Significant economies of scale also remain to be achieved by sharing computer hardware.

Question. I understand you have estimated $15 million could be saved the first year, and $102.6 million over 3 years, by requiring the larger two-thirds of Medicare contractors to share computer processing and maintenance costs. Could you briefly describe how such a proposal would work?

Answer. Actually, the proposal we are working on would apply to all contractors, but would vary the requirements according to claims volume. Smaller Medicare contractors would have to enter into shared processing arrangements; that is, a number of contractors would use the same computer to process all claims from their combined jurisdictions. All other functions would be retained on an individual basis. This eliminates the costs of multiple computer operations as well as requiring only a single set of claims processing software. For large scale contractors, we would permit them to retain their own computer operations, but require them to share claims processing software with other contractors. A single contractor or commercial vendor would provide maintenance support to all users. HCFA envisions that there could be a number of such processing and

maintenance arrangements. It is not our intention to move to a single national system.

CONSOLIDATION OF COMPUTER WORK

Question. What prevents you from moving administratively to save the taxpayers money through more efficient utilization of computer technology?

Answer. HCFA has already taken action in this direction. We have adopted a policy for certain critical functions such as inpatient hospital claim pricing, of requiring all contractors to use software prepared directly for HCFA by integrating it into their own systems. We have used our budgetary authority to steer contractors needing new systems to shared maintenance in their requests for proposal. We have articulated our desire for contractors to move to shared processing and shared maintenance very clearly to the contractors and no longer fund changes not specifically required by law or HCFA instructions to independently maintained systems. However, unless a contractor needs HCFA approval for a procurement or funding for modifications to the system, persuasion is the only inducement.

Question. Have you explored utilizing the rule-making process to implement consolidation of data centers?

Answer. Computer processing of Medicare claims and the systems used for this purpose are not referred to in Medicare legislation. Historically, system selection has been within the discretion of contractor management. We have discussed the options available to HCFA within the Department and believe that rule-making could not be sustained in the face of assured legal challenge. In the absence of Congressional guidance and intent, it might well be found to be anti-competitive. We therefore have limited our efforts to those actions where our authority is clear, such as budget review and approval.

COMPARISON OF VA AND MEDICARE OXYGEN SUPPLIES

The Inspector General's report has examples of the same company supplying identical oxygen concentrations to the Veterans Administration and Medicare, in the same geographic area. Under the VA competitive bid process, the supplier was paid $78 per month rental, while Medicare paid $300 per month rental. To quote the Inspector General's report, "...Medicare's payments for the rental of oxygen equipment were typically two to four times the amount paid by the VA hospitals using competitive bid contract procedures." The report went on to state, "...Almost all VA hospitals using competitive bid contracts for oxygen services were

complimentary of the quality of products and degree of maintenance and other services rendered by their contractors."

Question. If you applied your 5 percent cut proposed to this area, Medicare would still pay $285, compared to VA's $78. Don't you think these results merit your trying competitive bidding, which the Inspector General says could save $200 million annually?

Answer. HCFA is precluded by section 4062 of OBRA 87 from using a competitive bidding methodology or any other methodology, other than the fee schedule methodology provided for in law, until January 1, 1991. At that time, HCFA will be authorized to use inherent reasonableness authority. HCFA is also precluded by section 4062 from conducting any demonstration project respecting alternative methods of payment, such as competitive bidding, for medical equipment.

Question. Why not at least experiment with competitive bidding in a few regions of the country?

Answer. HCFA is precluded by section 4062 of OBRA 87 from conducting any demonstration project respecting alternative methods of payment such as competitive bidding, for medical equipment.

Question. Is there any reason why you couldn't subcontract with the Veterans Administration to purchase oxygen for Medicare?

Answer. Although we know of no specific prohibition against such activity, we know of no specific authority in the Medicare statute that would allow HCFA to make such a contract with the Veterans Administration or that would allow HCFA to require beneficiaries to use the Veterans Administration as their oxygen supplier.

NEED FOR STRONGER ACTION TO REDUCE OXYGEN COSTS

The Inspector General's report notes that you issued voluntary guidelines to Medicare contractors in March 1987, which, if fully implemented, could save over $100 million annually. Yet, the contractors are not eager to create local charge levels, believing equipment issues should be dealt with nationally.

Question. In view of this reluctance to voluntarily carry out your 1987 guidelines, why don't you propose a nationwide payment limitation for oxygen concentrators?

Answer. HCFA has had no such reluctance. HCFA had issued Medicare Carrier Manual instructions in March, 1987 urging carriers to closely review the pricing of oxygen concentrators. The example contained in the instructions suggested a reasonable allowance of $190 for a concentrator. However, OBRA 87 mandated the use of calendar year 1986 as the base for the oxygen fee schedule. Therefore, any actions after 1986 to reduce payment for concentrators have no effect on the schedule. It was for this reason that HCFA strongly urged, in light of the more extensive overpricing of oxygen concentrators, that the legislation provide for more than a 5 percent reduction in the fee schedule rates. This effort was unsuccessful. Moreover, section 4062 effectively precludes the use of inherent reasonableness until 1991 and this effectively eliminates any ability absent statutory change to deal with this problem. Congressional actions to restrict competitive bidding demonstration further inhibit our ability to control these expenditures.

Question. Isn't it time to fix this problem, which has dragged on for years, once and for all?

Answer. Yes, however, we cannot fix the problem without legislative change.

PROCESSING MEDICARE CLAIMS

The Physician Payment Review Commission has recommended that Congress require doctors to submit all Medicare claims electronically. This would not only relieve older citizens of the burden of submitting their own claims, but save the Federal government money.

Question. How much would be saved if all Medicare claims were processed electronically?

Answer. If all assigned claims were processed electronically about $55.8 million could be saved annually. Unassigned and beneficiary prepared claims are not adaptable to full electronic processing.

Question. What are the impediments to getting more doctors to voluntarily submit Medicare claims electronically?

Answer. Historically, Medicare's primary incentive to encourage physicians to submit claims electronically has been faster payment. OBRA 87 mandated a 14 day floor in paying physician and supplier claims. This built-in delay in paying claims acts as a disincentive to encouraging increased use of electronic media claims. In addition, Medicare does not pay for equipment and software. Accordingly, providers and

suppliers with low to medium Medicare volume have no incentive to invest in expensive hardware and software. Legislation frequently changes Medicare coverage and reimbursement policy, consequently the information required with the claim does not remain static. The Medicare Catastrophic Coverage Act of 1988 and other recent legislation has changed program requirements enough to require a substantial revision to both the Part A and Part B electronic claim submission formats.

EXCESSIVE AMBULANCE COSTS UNDER MEDICARE

Last month I held a special oversight hearing which included testimony from several Medicare contractors. The representative from South Carolina's Blue Cross/Blue Shield organization told how helicopters were frequently used for non-emergency transfers of patients between hospitals, costing three times more than routine ambulance service. Now, Inspector General Kusserow estimates savings of $109 million could be achieved by limiting excessive charges even for ground ambulance services.

To illustrate potential savings, he cites examples such as the case where Medicare pays an ambulance company $106 per trip from a hospital to a diagnostic center, even though the same hospital pays only $55 for the same trip for non-Medicare patients.

Kusserow identified one Medicare contractor that is already achieving savings of 15.8 percent, using existing administrative authority. In a sample of six States, the Inspector General found the Veterans Administration is obtaining rates averaging 25 percent lower than Medicare payment rates, without adversely affecting the quality of ambulance services.

Question. What actions have you taken in response to the Inspector General's recommendations to curb ambulance costs?

Answer. First, we should clarify that the impetus for the OIG report was provided by an earlier memorandum from HCFA to the Inspector General. It was our belief that a study of ambulance services would enable us to get a sense of the problems associated with Medicare coverage and reimbursement policies.

The centerpiece of the draft OIG report was the recommendation to seek legislative authority to permit competitive bidding. We have a number of concerns about the OIG proposal.

Question. Why don't you require Medicare contractors to use their existing "inherent reasonableness" authority to limit ambulance charges?

Answer. Prior to the inception of the OIG study, the inflation indexed charge (IIC) was introduced as an additional reasonable charge factor. Effective October, 1985, ambulance rates were frozen at the levels in effect in September, 1985. (It bears noting that those rates were based on suppliers' 1983 charges.) Subsequent rate increases, allowed in January, 1987 and 1989, have been limited by the Consumer Price Index.

Because the OIG study did not take the IIC into account, we have strong reason to believe that the cost savings identified in the report may be overstated. For example, the analysis of savings was based on the difference between existing Medicare rates and anticipated rates assuming no IIC limits.

Additionally, the OIG recommendations with respect to inherent reasonableness concentrated on the efforts of one carrier - Empire Blue Shield of New York city. It is unclear whether circumstances applicable to that particular carrier are representative of all Part B carriers. Among the concerns we conveyed to the OIG was the need for additional details on this and other aspects of their study in order to develop a meaningful plan for requiring the use of inherent reasonableness authority to lower payment levels. If rates are excessive in certain localities, we would certainly want carriers to apply inherent reasonableness to effect payment reductions. To date, the OIG has not responded to our comments, but we would welcome their response so that such a plan could be jointly worked out.

Certainly, one of the criteria that should be used in determining the appropriate use of inherent reasonableness is the situation described, i.e., where ambulance companies bill different rates to Medicare carriers, we would expect carriers to include that data in their rate-setting analysis. We might add that the OIG has authority under section 1128(b)(6) of the Social Security Act to sanction such providers, and would encourage them to do so where their findings indicate the existence of this practice.

EXCESSIVE AMBULANCE COSTS UNDER MEDICARE

Question. Why not follow the Veterans Administration's approach and seek legislative authority to allow Medicare contractors to use competitive bidding to set ambulance reimbursement rates?

Answer. Competitive bidding by Medicare may raise issues of timeliness, availability and quality of care provided to Medicare beneficiaries in emergency situations. Therefore, it may be preferable to conduct a demonstration to collect the data needed to insure continued high quality and timeliness of emergency

medical transportation received by Medicare beneficiaries before seeking legislative authority.

MEDICARE PAYS HIGHER LAB FEES THAN SOME PHYSICIANS

Even though Medicare pays a major share of our Nation's health care costs, it does not necessarily pay prices that are comparable or at least as low as those paid by some physicians. In some cases, independent medical laboratories give "deep discounts" to some physicians; they claim that their cost of doing business with these physicians is much lower than their costs of doing business with Medicare. In these situations, the laboratory's testing charges to physicians are much lower than the charges allowed under fee schedules established by Medicare.

I understand that some laboratories charge Medicare significantly more than they charge private physicians for the same test.

Question. To what extent is this practice occurring?

Answer. We believe most physicians are able to obtain such tests at lower levels than the fee schedule amounts. Although we are aware of this dual pricing practice, we are not able to provide an accurate estimate of its extent. However, based upon a sample of 18 laboratories, preliminary findings of an OIG priority audit memorandum indicate that laboratories on average charge more to Medicare for clinical diagnostic laboratory tests than laboratories charge physicians for the same test.

Question. Does it make sense to have Medicare fee schedules that allow medical laboratories to charge Medicare substantially more than the amounts charged to physicians?

Answer. This differential charging practice does not make sense. We would note that laboratories claim that Medicare testing entails more administrative costs than non-Medicare testing. We have asked the OIG, if at all possible, to ascertain what billing cost differentials exist between tests run for Medicare beneficiaries and those run for other patients of the same physicians. This information would enable us to present a complete case since rebuttal of the laboratories' contention or quantification if its validity is required.

CATASTROPHIC HEALTH INSURANCE

A significant number of Iowans have expressed concern to me about the way benefits under recently

enacted Medicare catastrophic health insurance legislation are to be financed. Yet a poll conducted by the American Association of Retired Persons shows 65 percent of persons 65 and older support the new law, and only 21 percent say they oppose it. One of the problems seems to be that there is a lot of misunderstanding about the costs and benefits of Medicare catastrophic health coverage.

Question. Do you have an easy-to-understand "conversion chart" so people can see what they can expect to pay, based on their income, compared to the value of benefits?

Answer. One of our top priorities in the implementation of the Catastrophic provisions is to ensure that Medicare beneficiaries understand all aspects of these new and expanded benefits. Our efforts to increase beneficiary awareness have included mailings to all beneficiaries of a special catastrophic notice and a new Medicare Handbook. Each of these items describes the catastrophic benefits as well as the beneficiary's share of the costs.

As you know, with the unique financing of the catastrophic program, the specific premium amount paid by a beneficiary will depend on his or her tax liability. The Department of Treasury (IRS) is responsible for developing the "official" income distribution charts for use in filing tax returns. We recommend that you refer your question to IRS.

Question. What are you doing to educate Medicare beneficiaries about the catastrophic health care law?

Answer. In FY 1988, HCFA spent approximately $13.2 million in promoting and educating the Medicare beneficiaries and the health care community, in general, on the Catastrophic Health Insurance Program. HCFA mailed a revised Medicare Handbook to more than 32 million beneficiaries, in addition to producing and mailing several informative notices, pamphlets, and fliers. HCFA even provided TV and radio public service announcements and installed two national hotlines, which had received about 300,000 calls as of March 25, 1989. In FY 1989 and FY 1990, HCFA plans to spend approximately $15.0 million annually on this effort.

PRESCRIPTION DRUG BENEFITS PROGRAM

Starting in 1991, Medicare will begin paying for part of the costs for outpatient prescription drugs used by the elderly and disabled. There is obviously an enormous amount of work to be done between now and then to make sure that you have an administrative structure in place so that millions of claims for medications are paid swiftly and accurately.

Question. How much progress have you made so far in developing a new claims processing system to handle prescription drug claims?

Answer. We have made substantial progress in developing a new Medicare prescription drug claims processing system. On October 13, 1988, we published a request for information in the Commerce Business Daily to implement the provisions of the law. In that document, we set forth a description of our thinking on the approach to establishing the system and asked for public comment. On November 21, 1988, we sponsored a national meeting with over 600 industry representatives to further discuss the system and receive questions and comments. By the close of the comment period for the notice in the Commerce Business Daily, 77 individuals and organizations responded.

We have also met with numerous private companies and organizations involved in the prescription drug industry and electronic data processing fields. Staff have traveled across the country to gather knowledge of the current level of expertise in this area. Within HCFA, we have contracted with several consultants to assist us in our information gathering and to help with the system we are building.

We have established an ambitious, yet we believe, achievable schedule to implement this program. Our tasks in the first part of that schedule have already been completed. We are proceeding on schedule, with the issuance of the Request for Proposal (RFP) for the procurement of the drug bill processors who will be our contractors operating the system, the awarding of the contracts and the implementation and operations phase of the contracts. The RFP is scheduled to be released in August and contracts awarded in order to assure timely implementation of the program. The implementation phase will cover the calendar year 1990 and we expect the system to be fully operational by January 1, 1991.

PRESCRIPTION DRUG BENEFITS PROGRAM

Question. Can you tell us how you have decided to divide up the country into claims-processing regions for this activity and where those regions will be?

Answer. The procurement rules under the Federal Acquisition Regulation for full and open competition preclude the release of this information at the present time. A complete description of that geographic breakdown will be included in the RFP to procure the services of our drug bill processors.

Question. How have you decided to delineate responsibilities between your existing contractors and those who will select to exclusively handle prescription drug claims?

Answer. To date, our thinking has been that drug bill processors will be responsible for almost all the functions related to the processing of over 700 million prescription claims for the approximately 34 million Medicare beneficiaries. This will include the following functions:

- o Receiving, maintaining and updating eligibility and drug utilization files of 34 million eligible Medicare beneficiaries.
- o Maintaining the current status of the variable annual drug deductible for each beneficiary.
- o Interfacing electronically with each other, with other Medicare contractors and with the HCFA data center using standard electronic formats and protocols.
- o Operating electronic POS and paper drug bill processing and reimbursement systems.
- o Enrolling and maintaining professional relations with over 55,000 participating retail pharmacies, mail order houses and dispensing physicians.
- o Conducting an integrated program of pre- and post-payment drug utilization review.
- o Conducting pharmacy audits.

There will be some overlap of functions such as in the appeals process whereby questions may be handled by the drug bill processors, but formal appeals will be processed by the Medicare Part B carriers.

MEDICARE PEER REVIEW ORGANIZATIONS (PROs)

You spend more than $150 million annually on contracts with Medicare Peer Review Organizations (PROs). These PROs are supposed to review the appropriateness and quality of health care provided to Medicare beneficiaries. Reports from GAO point out generally lackluster actions by PROs in response to quality of care problems, and your Inspector General's office estimates that $1.2 billion could be saved by denying payment for poor quality care rendered to Medicare beneficiaries.

Question. How serious is the problem of weak and ineffective PROs?

Answer. The General Accounting Office has not reviewed the effectiveness of PRO decisions. The DHHS Office of the Inspector General (OIG) report cited by

the committee is not a current analysis and valid criticisms raised by the OIG have been remedied with corrective actions. HCFA did not accept all the conclusions of the OIG report, since many of its findings were based on re-reviews of PRO decisions by out-of-area physicians, not local peers.

HCFA has found that, overall, PROs have proven effective in controlling unnecessary hospital utilization. Equally important, our analyses of premature discharges, the results of applying generic quality screens, readmissions, PRO quality interventions, sanctions and the PRO objective setting process support the position that PROs have been effective in assuring that beneficiaries receive care that meets nationally-recognized standards.

MEDICARE PEER REVIEW ORGANIZATIONS (PROs)

Question. What actions have you taken to date to insure that PROs aggressively safeguard the quality of health care provided to Medicare beneficiaries?

Answer. The PROs are evaluated based upon reviews performed by HCFA regional office personnel, by an independent contractor, and by central and regional office analyses of PRO data reports. When deficiencies in PRO performance are identified, the regional project officer issues a request for a Corrective Action Plan (CAP). If a PRO fails to submit an acceptable CAP or to comply with an approved CAP within the HCFA required timeframes, additional corrective action is requested and HCFA considers withholding payment or initiating termination of the PRO contract. HCFA also analyzes PRO performance against published criteria to determine whether or not a PRO should be eligible for non-competitive renewal of its contract.

Question. Have you analyzed the wide variations between PROs, and identified particular problem areas?

Answer. Yes. We analyzed both the wide variation in problem identification and quality interventions taken by PROs under the second Scope of Work (SOW). As a result of this analysis, several actions were taken to improve performance in these areas. Thus, the third SOW, which was implemented April 1, incorporates changes to correct those variations.

A task force of PRO and HCFA personnel met in a series of consensus-building meetings to develop improved inpatient hospital generic quality screens. These screens are used as guidelines to identify potential quality problems for more intensive review. As a result of these meetings, improved screens were developed for implementation in the third SOW. We believe that this will improve the consistency of PRO identification of quality problems.

In the past, each PRO developed its own Quality Intervention Plan (QIP), including severity levels, intervention steps, triggers, etc. This autonomy led to a lack of consistency across PROs. Therefore, a task force made up of PRO physicians and HCFA personnel was convened to develop a national QIP. The purpose of the QIP is to improve the uniformity of PRO actions across the nation. All PROs will apply uniform severity levels to confirmed quality problems, and apply uniform interventions based upon the number and severity of the problems identified.

MEDICARE PEER REVIEW ORGANIZATIONS (PROs)

Question. What measures could improve the effectiveness of PROs in rural areas?

Answer. We assume that this question relates to the Office of the Inspector General (OIG) report which indicated that poor quality care was more prevalent in rural hospitals.

In response to this report, we sent the involved PROs a list of those hospitals where the OIG identified high rates of problems for utilization, quality, or both utilization and quality. The PROs are to utilize this information along with the results of their ongoing reviews in these hospitals to determine whether interventions should be initiated. This process will help the PROs in identifying and resolving quality problems in these rural hospitals.

Question. Tell us what results you expect to achieve from proposed new rules which were published this January in the Federal Register.

Answer. The proposed rule published in the Federal Register will implement section 9403 of the Consolidated Omnibus Budget Reconciliation Act of 1985 which authorizes PROs to deny payment for care which is determined to be of substandard quality.

This denial action will be taken by the PROs when a serious quality problem is identified which either has an actual adverse effect on the patient or meets the definition of a gross and flagrant violation of a provider's obligations (i.e., presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in a high-risk situation).

When less severe quality problems are identified, PROs take interventions other than denial of payment.

Although denials of payment are punitive, we believe that Congress intended that this provision would modify aberrant practice patterns leading to substandard care, thus improving the quality of health care.

POTENTIAL MEDICARE SAVINGS

From our recent oversight hearings, we learned that Medicare contractors are not providing information that could be used to save millions of dollars. This information would allow auditors to match data on private insurance coverage with Medicare records to make sure Medicare is the secondary payer. Not everybody realizes that Medicare may be duplicating payments which should be made first by any private insurer.

Question. Why don't you simply require that Medicare contractors use data which is readily available, to identify Medicare as the secondary payer, and seek recoveries?

Answer. Medicare contractors are required to use all available information to identify Medicare Secondary Payer (MSP) situations. For example; contractors search HCFA's records to see if a continuing MSP situation, such as employer health insurance coverage, has been identified in the past. If so, the claim is not paid until it is proven that the employer health insurance coverage no longer exists. Claims involving trauma-related diagnoses or procedures are developed to see if the services are related to a work accident or injury or an automobile accident. Contractors are required to seek recovery of payments when another insurer should have paid prior to Medicare.

Despite HCFA's best efforts, some MSP situations are not identified. One way that MSP situations could be identified would be to have insurers, underwriters and third party administrators of employer health plans identify covered Medicare beneficiaries who are 65 or older and employed, or the spouse of an employee of any age; who have end stage renal disease; or who are disabled and the family member of an employee or who qualify as an employee. The Secretary currently does not have authority to require such reporting.

In an effort to identify MSP situations where a Medicare contractor may be the insurer responsible for primary payment, HCFA will propose a contract amendment that will require contractors to match their insurance records with their Medicare records. Such an amendment is being negotiated with the contractors.

NOTE: Subsequent action has made $7.5 million available from the contingency to enable HCFA to undertake neogiations with its contractors in FY 1989 in order to match their insurance records with their Medicare records.

POTENTIAL MEDICARE SAVINGS

Question. What amount of savings is currently lost due to poor compliance with the requirement making Medicare the secondary payer?

Answer. The exact amount lost due to poor compliance is obviously not known and is difficult to determine. We estimate cumulative overpayments could exceed $1 billion.

ACCREDITATION COSTS -- A FEDERAL RESPONSIBILITY?

Hospitals that participate in the Medicare program and reimbursed by the Health Care Financing Administration (HCFA) are oftentimes accredited by the Joint Commission on Hospital Accreditation. Generally speaking, hospitals are responsible for paying the fees associated with the accreditation process.

On the other hand, some Medicare patients obtain health care services at facilities or from laboratories that are not accredited or certified by any National organization. This fiscal year HCFA will reimburse the States over $75 million to conduct survey and certification activities and over $5 million to certify high volume physician office labs. In these cases, HCFA would appear to be incurring a cost that should more properly be borne by these operators of these facilities.

Question. To what extent is HCFA, in effect, acting as the accrediting or licensing agency when health care facilities or laboratories do not obtain their own accreditation or licensure?

Answer. HCFA is not an accrediting or licensing agency. HCFA, in accordance with section 1864 of the Social Security Act, reimburses State survey agencies for making certification recommendations to HCFA about providers and suppliers, including clinical laboratories, that must meet health and safety standards in order to participate in the Medicare/Medicaid programs.

HCFA also pays State survey agencies out of its Medicare/Medicaid budget to inspect clinical laboratories licensed under the Clinical Laboratory Improvement Act (CLIA). The only exceptions to using the State survey agencies for survey and certification activities are that hospitals accredited by the Joint Commission and the American Osteopathic Association are "deemed" to meet the Medicare/Medicaid requirements.

Also, under CLIA, laboratories accredited by the College of American Pathologists and licensed by the State of New York are exempted from CLIA licensure.

However, CLIA was amended October 31, 1988 to require that all clinical laboratories pay for the administrative, survey and monitoring costs of approving their laboratories for CLIA purposes. The CLIA provision would also encompass all Medicare/Medicaid clinical laboratories including physicians' office laboratories. HCFA is developing regulations to collect fees from laboratories to implement the CLIA provision which became effective January 1, 1989.

ACCREDITATION COSTS -- A FEDERAL RESPONSIBILITY?

Question. Should HCFA devise a way to recover these costs through Medicare/Medicaid billings?

Answer. Currently, with the exception of the CLIA provision, HCFA has no statutory authority to impose user fees. Existing statutory authority for funding the Medicare/Medicaid programs would need to be revised to allow for the imposition of user fees, before any money could be collected from providers and suppliers for survey and certification costs.

ACCESS TO HEALTH CARE

There is no health issue more basic and more vital than access to care. In rural areas, the cornerstone of the health care system is the hospital. Without rural hospitals, there just isn't access to care.

Since 1980, over 200 rural community hospitals have closed, and another 500 are on the edge right now. In order to respond to the rapid changes in health care, many rural hospitals need to rethink their mission and restructure how they deliver services.

Question. How is the Department helping rural hospitals respond to the changes of the past few years, and the changes still to come in health care?

Answer. The problems facing rural hospitals are complex; declining population, economic recession, and residents seeking care in urban centers have made it difficult for some hospitals to remain viable. While we recognize the struggle of many rural hospitals, we do not believe that Medicare should be viewed as the sole means of their survival. Recent congressional and administrative actions haveimproved the financial position of rural hospitals under Medicare. In the past few years, differential outlier payments, case weighted payment rates, and differential updates have assisted rural hospitals under PPS. For FY 1990, the Secretary again recommends a differential update for rural hospitals. We also propose relaxing the criteria for qualification as a sole community hospital, to better assure rural access to care. In addition, we

are undertaking a number of initiatives to help rural hospitals and their communities develop creative alternatives to traditional delivery systems. Within the Public Health Service, the Office of Rural Health Policy also has been active in targeting services for and promoting alternatives to traditional health care delivery in rural areas.

ACCESS TO HEALTH CARE

Question. What steps are you proposing to ensure access to care for children, families, and for Medicare beneficiaries who live in rural areas -- they pay the same premiums as folks who live in cities?

Answer. We are undertaking several activities to improve the access to, and quality of, health care delivery in rural areas. Our activities include: a new grants program to assist small rural hospitals and their communities in implementing projects to strengthen the capability of these hospitals to provide high quality care to Medicare beneficiaries; a demonstration program in Montana to develop alternative care facilities in frontier areas; a demonstration program in Texas to develop a telecommunications system with urban physicians and hospitals to provide continuing medical education to rural physicians; and evaluating ways to assist rural hospitals that are the sole providers for care in their community.

RURAL FAMILIES AND MEDICAID

Medicaid is supposed to be our "safety net" in health care, yet only one-fourth of the rural poor qualify for Medicaid, compared to 43% of the poor in inner cities. The problem here is that rural families are more likely to stay together, which disqualifies them from receiving Aid to Families with Dependent Children. Another complicating factor is that families with a little land or a car won't meet Medicaid's strict assets test. But it's nearly impossible to get along in rural areas without a car.

RURAL FAMILIES AND MEDICAID

Question. President Bush has proposed expanding Medicaid eligibility to increase access to care for women and children. Will the Administration also seek to expand Medicaid eligibility to the rural poor?

Answer. We believe that our initiative for pregnant women and children will be extremely valuable in rural areas because the health status of those who are underserved can be improved by focusing first on those who are at greatest risk: lower income pregnant women and children. An estimated one-third of those without health insurance are children and helping them get a healthy start in life is vitally important.

The Family Support Act of 1988 extends transitional Medicaid assistance for up to 12 months to families leaving AFDC for work. It also mandates Medicaid for 2-parent families, when the principal wage erner is unemployed, even if States choose to limit the time period for AFDC cash assistance. Many rural States did not previously provide assistance to these families when the program was optional, and we expect this mandate to lead to a significant increase in coverage.

We are also submitting a number of legislative proposals. The first proposal would require States to enroll in Medicaid an estimated 240,000 more low-income pregnant women and children (with incomes up to 130 percent of the Federal poverty level rather than 100 percent) and to expand coverage sooner than current law would permit (by April 1, 1990 rather than July 1, 1990). The second proposal would provide presumptive eligibility for Medicaid for up to 60 days to these low income pregnant women, in order to encourage them to receive prenatal care as early as possible in their pregnancies while eligibility for Medicaid is formally determined. The third proposal would require States to provide Medicaid coverage of immunizations for children under age 6, even if they were not otherwise Medicaid eligible, who by present a Food Stamp eligibility card.

We are also planning to fund projects in States to demonstrate innovative approaches to reducing infant mortality and morbidity, with emphasis on case management, outreach, and increased provider participation. These demonstration objectives recognize and attempt to find more effective ways of addressing barriers to health care that are often particularly troublesome in rural areas.

All of these proposals and initiatives will be financed through savings achieved under a fourth legislative proposal which would gradually phase out enhanced match rates for most administrative costs.

With regard to your concern about Medicaid eligibility for intact families, as you know, that is tied to AFDC eligibility. States have a certain amount of flexibility on this, but generally speaking the value of the home is excluded, and the first $1500 in equity value of one automobile is also excluded from the assets computation. The equity value of income-producing property is counted, because individuals are expected to pay for their own support if they are able, so that scarce public resources can be devoted to those in greatest need. States do have the option to provide additional Medicaid coverage by establishing a medically needy program for individuals who would be eligible, except that they have too much income, if they have extraordinarily high medical expenses.

HCFA RESEARCH AND DEMONSTRATIONS

When we passed the budget reconciliation bill in 1987, we included a provision to set-aside 10 percent of the HCFA Research and Demonstration budget for rural research. The Department opposed that provision. Then Congress and the Department went a couple of rounds over what the set-aside really meant, but in the end we all agreed to it.

Question. What research has been conducted under the 10 percent set-aside?

Answer. HCFA has funded the following projects focusing primarily on health care in rural areas:

- Preventive Health Services for Medicare Beneficiaries (University of Pittsburgh); sites are located in rural areas;
- Economy and Efficacy of Medicare Reimbursement for Preventive Services (University of North Carolina); approximately one-third of sites are in rural areas;
- Evaluation of National Rural Swing Bed Program (University of Colorado);
- Medical Assistance Facility (Montana Hospital Research and Education Foundation);
- Refining the Geographic Practice Cost Index: Implications for Urban and Rural Areas (The Urban Institute);
- Urban/Rural Differences in Physician Practice Patterns (Brandeis Research Center);
- Research Agenda on Rural Health (National Center for Health Services Research)
- PPS impact on Rural Hospitals (Center for Health Economics Research)
- Health Manpower Shortage Areas (Brandeis Research Center);
- MEDNET Telecommunications Network for Urban and Rural Areas (Texas Tech), funded jointly with HRSA; and
- Grant Program for Rural Health Care Transition (grants to be awarded in FY 1989).

We have also included in our grant/cooperative agreement solicitation for FY 1989 an increased emphasis on rural health care issues, particularly in the areas of hospitals, physicians, and quality/access

to care. Awards under this solicitation (which closed April 3) are expected by early September.

HCFA RESEARCH AND DEMONSTRATIONS

Question. Do you plan to continue setting aside 10 percent of HCFA's research and demonstration projects for rural research and demonstrations?

Answer. Rural health care issues are of interest to both HCFA and the Department. Specific steps are being taken currently to continue to target 10 percent of research funds in FY 1990 for projects that relate to rural health care issues. HCFA convened a panel of experts on rural health care to help develop the future agenda. HCFA has also increased the emphasis on rural health care issues in our statement of funding priorities and solicitation for new projects for FY 1989 and will do the same for FY 1990.

HCFA RESEARCH AND DEMONSTRATIONS

Question. Will the Department support legislation to continue the 10 percent set-aside?

Answer. We believe that our rural health care initiatives have been and continue to be a Department priority. In addition, much of our research has a rural component, and earmarking an arbitrary 10 percent of HCFA's research and demonstration funds is unnecessary.

Question. Please provide the subcommittee with a budget for and list of projects currently underway, projects completed, and future rural research and demonstration projects planned.

Answer. Because the Medicare Catastrophic Coverage Act of 1988, which amended OBRA 1987 to include a target set-aside for rural issues in FY 1988, as well as FY 1989 and FY 1990, was not passed until late in FY 1988, HCFA did not focus its FY 1988 project solicitation on studies of this type. Therefore, an adequate number of proposals were not received to meet the 10 percent target in FY 1988. HCFA did spend $1 million on rural projects in FY 1988. In FY 1989 and FY 1990, HCFA has targeted 10 percent of their research funds for rural health projects.

Following are lists of projects completed, projects underway, and future projects planned for rural research.

Rural Projects Completed

- Uncompensated Care Costs in Large Rural Teaching Hospitals (Brandeis Research Center)

- Sole Community Hospitals (Brandeis Research Center)

- Long Term Care Impact of PPS on Rural Hospitals (Brandeis Research Center)

- Research Agenda on Rural Health (National Center for Health Services Research)

HCFA RESEARCH AND DEMONSTRATIONS

Rural Projects Currently Underway

- PPS Impact on Rural Hospitals (Center for Health Economics Research)

- Preventive Health Services for Medicare Beneficiaries (University of Pittsburgh); sites are located in rural areas;

- Economy and Efficacy of Medicare Reimbursement for Preventive Services (University of North Carolina); approximately one-third of sites are in rural areas;

- Evaluation of National Rural Swing Bed Program (University of Colorado);

- Medical Assistance Facility (Montana Hospital Research and Education Foundation);

- Refining the Geographic Practice Cost Index: Implications for Urban and Rural Areas (The Urban Institute);

- Health Manpower Shortage Areas (Brandeis Research Center);

- MEDNET Telecommunications Network for Urban and Rural Areas (Texas Tech), funded jointly with HRSA; and

Future Rural Research Projects Planned

- Grant Program for Rural Health Care Transition (grants to be awarded in FY 1989).

- We have included in our grant/cooperative agreement solicitation for FY 1989 an increased emphasis on rural health care issues, particularly in the areas of hospitals, physicians, and quality/access to care. These projects include:

    + How beneficiary access to hospital care in rural areas may have changed as a result of PPS;

+ Physician practice variations in large versus small and urban versus rural areas and their implications for Medicare expenditures;

+ Analysis of the behavior of health plans across geographic areas, i.e., between rural and urban areas;

+ Studies to examine the financial status of various classes of rural and urban inner city hospitals; and

+ Studies of the impact on access to care and population health status where rural hospitals have closed, including the effect on access by the elderly and the poor.

HOSPITAL COSTS

In my home state of Iowa, the bill for inpatient hospital care in 1987 came to over $1.1 billion. Of that amount, 34 hospitals in urban communities received 86% ($950 million), while Iowa's 93 rural hospitals received only 14% ($159 million).

Rural hospitals practice a more "conservative" type of medicine; they use less services, and therefore provide less costly care than urban hospitals. I would think your Department should encourage this kind of sensible care.

It seems to me that if we want to control costs, we need to concentrate on the group of hospitals that are getting 86%, and not on the group that's only getting 14%.

Question. Do you think it's fair that urban hospitals account for about half of PPS hospitals, but receive over four-fifths of Medicare payments. In addition to receiving higher DRG payments, urban hospitals get most of the additional payments teaching, "disproportionate share," and outliers.

Answer. Medicare essentially pays providers of hospital care for the allowable costs of covered services, whether on a prospective or retrospective basis. The Prospective Payment System (PPS), like other methods of payment, implicitly recognizes such allowable differences as the input costs of hospital care, the impacts of a teaching system on patient care, and differences in the complexity of care needed by patients. While the system does not perfectly select only allowable costs for needed services, we believe that PPS is a relatively fair payment mechanism in general.

Both the Congress and HCFA have noted the more restrictive financial impact of PPS on a number of classes of hospitals, with rural hospitals a primary class of concern. Since the inception of PPS, numerous legislative and administrative measures have been taken to provide financial relief to rural hospitals. The measures include separate urban and rural outlier offsets, to reflect the fact that the majority of outlier cases occur in urban hospitals, case weighting in lieu of hospital weighting of standardized amounts, which results in a higher rural payment rate relative to the urban rate, and differential updates which favor rural hospitals.

We continue to consider PPS adjustments that would improve the access to and quality of care for Medicare's rural beneficiaries. We suggest, however, that Medicare payment alone cannot address the more general problems of low rural hospital occupancy rates and adverse rural economic trends.

HOSPITAL COSTS

Question. Do you support eliminating the urban-rural differential in DRG payments?

Answer. We are examining changes in PPS to further address the financial problems of rural hospitals. In particular, we are focusing our research on developing measures of severity and other factors that would explain hospital cost differences and would allow us to replace the current urban-rural differential with a single rate adjusted for these factors.

PHYSICIAN-HOSPITAL LINKAGES

Your agency issued proposed regulations in January pursuant to the Medicare and Medicaid Patient Protection Act of 1987 that would severely constrain relationships between hospitals and physicians. The regulations are meant to encourage competition by preventing hospitals from buying or partially funding physician practices in order to create a pipeline for patient referrals.

I understand the need to prohibit anti-competitive relationships in competitive markets. However, in rural communities, the issue is not competition, but access. In these areas, we need to encourage linkages between hospitals and physicians, not prohibit them. It's the best way to keep hospital and doctors servicing the community. When a hospital helps a physician with rent, malpractice premiums, or other expenses, it stabilizes the practice. That benefits the community. For rural areas, the important point is not competition, but continuity of care.

PHYSICIAN-HOSPITAL LINKAGES

Question. How will you assure that these regulation do not outlaw relationships between rural hospitals and doctors that promote quality and efficient services?

Answer. The proposed regulations published in January are not intended to, and do not, prohibit or outlaw specific business arrangements or relationships. Rather, the regulations have been designed to carve out and identify so-called "safe harbors" that would guarantee providers protection from the risk of prosecution if their relationships or arrangements meet the prescribed standards. The Federal anti-kickback statute itself prohibits the offering, payment, solicitation or receipt of anything of value intended to induce the referral of business reimbursable under the Medicare and Medicaid programs.

The proposed regulations establish "safe harbors" in the following eight broad areas:

1. Investment interests - To reflect the view that Congress did not intend to bar absolutely an investment by physicians in other health care entities to which they refer patients, a safe harbor has been included for investment interests in large public corporations where such investments are available to the general public. This safe harbor describes a minimum number of shareholders and a minimum number of assets which the company must have in order to qualify under this exemption.

2. Space rental - While many rental arrangements are legitimate, many situations exist where rental payments are simply a device used to mask payments and induce referrals. A safe harbor has been proposed for rental arrangements if the following conditions are met: access to the space is for periodic intervals and such intervals are set in advance in the lease, rather than based on the number of referred patients; the lease is for at least one year, so that it cannot be readjusted every month; and the charges reflect fair market value.

PHYSICIAN-HOSPITAL LINKAGES

3. Equipment rental - With the understanding that payment for the use of diagnostic and other medical equipment may simply be a vehicle to provide reimbursement for referrals, a safe harbor has been provided for certain situations involving equipment rentals similar to those applied to real estate rentals cited above.

4. Personal services/management contracts - While providers often have arrangements to perform services for each other on a mutually beneficial basis, some of these arrangements or payments may vary with the volume of referrals. A safe harbor provision has been proposed for joint ventures and other arrangements involving payments for personal services or management contracts, but only if certain standards are met and safeguards are present to limit the opportunity to provide financial incentives in exchange for referrals. This exemption includes the determination of whether services are paid at fair market value, and is predicated on the same type of standards and qualifications as set forth in the exemption for space and equipment rental.

5. Sales of practice - Unlike the traditional sale of a practice by a retiring physician, a physician may sell --or appear to sell -- a practice to a hospital while continuing to practice on its staff. Under these regulations, a safe harbor has been proposed for the sale of physician practices when they occur as the result of retirement or some other event which removes the physician from the practice of medicine or from the service area in which he or she was practicing, but not when the sale is for the purpose of obtaining an ongoing source of patient referrals.

6. Referral services - Professional societies and other consumer-oriented groups often operate referral services for a fee. Because such a service fee could be construed as a payment in order to obtain a referral, the proposed safe harbor provides standards and safeguards to assure that this exemption is not abused.

7. Warranties - It is in the public interest to have companies offer warranties as an inducement to the consumer to purchase a product. A safe harbor has been established for such purposes.

8. Discounts, employees, and group purchasing - Safe harbors relating to these three areas are specifically required by statute. The discount exemption is intended to encourage price competition and to have Medicare and Medicaid benefit from these reductions in price. The exemption would apply not only to individuals and entities who solicit or receive price reductions, but to those who offer or pay them. This discount exemption is limited to a reduction only in the amount a seller charges for a good or service to the buyer, either by a specified price break, or the inclusion of an extra quantity of the item purchased (at the time of purchase). The statutory exemption also permits an employer to pay an employee in whatever manner he or she chooses for

having that employee assist in the solicitation of program business and applies only to bona fide employee/employer relationships. The group purchasing organization (GPO) exemption would apply to payments authorized to act as a GPO for individuals or entities who are furnishing Medicare or Medicaid services. The exemption requires a written agreement between the GPO and the individual or entity that specifies the amount the GPO will be paid.

PHYSICIAN-HOSPITAL LINKAGES

Question. If the regulations are not changed to reflect the different nature of rural health care, will that compromise access to care?

Answer. No change to the regulations is needed. Where rural providers enter into financial relationships or arrangements intended to insure the continued viability of the rural health care delivery system, the statute prohibiting payments for referrals would not apply. However, where the purpose of the business arrangement appears to be to induce or reimburse for referrals, the rural provider should then be evaluated according to the same rules applicable to other providers -- either operate within the "safe harbor" standards or risk prosecution if all the circumstances are sufficient to prove that the purpose of the arrangement was to promote business and not to promote high quality and efficient health care delivery.

PHYSICIAN-HOSPITAL LINKAGES

Question. The Office of Rural Health Policy is mandated to work with you on regulations that affect a significant number of rural hospitals. What role has the Office of Rural Health Policy played in developing these regulations?

Answer. The Office of Rural Health Policy has developed a strong working relationship with the Health Care Financing Administration around its legislative and regulatory proposals and its policy development and research proposals. A formal Memorandum of Agreement was completed between the two organizations. As a part of this relationship, the office has provided recommendations on numerous issues within HCFA, ranging from support for a Montana demonstration that has been approved to convert small failing rural hospitals into community health facilities with short-term holding bed capacities ("Medical Assistance Facilities") to support for higher annual payment updates for rural hospitals.

Currently, the office is assisting HCFA in the design and implementation of a program of grants to rural hospitals to make transitions in their roles in the communities they serve.

RURAL HOSPITAL TRANSITION GRANTS

The Rural Hospital Transition Grants program helps rural hospitals meet the changing needs of their communities and continue to provide services. Last year, we provided a $9 million transfer from the Medicare trust funds for this program.

Question. Applications are not due to HCFA for another week (April 17), but I know that the applicants had to write a letter of intent. How many letters of intent did the Department receive?

Answer. We received approximately 1,100 letters from hospitals stating their intent to submit an application under this grant program.

The Governors' offices were to have submitted to HCFA the original applications which they received from hospitals applying for funding under the program. These submissions were to have been postmarked April 17. Based on the applications that have actually been received to date, we expect to receive approximately 700 applications from eligible hospitals.

RURAL HOSPITAL TRANSITION GRANTS

Question. How many grants do you expect will be made?

Answer. Congress appropriated $8,892,000 in fiscal year 1989 for funding this grant program (including evaluation of the program). Section 4005(e) of Public Law 100-203 (which authorized this demonstration program) provided that grants could be made for up to 2 years, with up to $50,000 being awarded each year. Given the 1-year appropriation, we decided to make grant awards up to the maximum authorized in legislation (i.e., $100,000 over a 24 month period). Consequently, we expect to make between 80-85 awards to hospitals under this grant program.

Question. When will the grants be let, and for how long?

Answer. We expect to be able to announce the awards by mid-September 1989. As stated above, awards will be up to the maximum period authorized in the legislation (24 months).

Question. Will the program develop new models of service delivery like the Medical Assistance Facility model in Montana?

Answer. The authorizing legislation provided eligible rural hospitals wide latitude in selecting the

type of specific project which would permit each hospital to most effectively address the problems it faced in providing care to Medicare beneficiaries. The Medical Assistance Facility model being developed in Montana is certainly one model of service delivery which hospitals could propose to develop under the grant program. Once the applications have been received and reviewed by the technical panels, we will be better able to assess the types of applications actually submitted.

Question. What kind of evaluations will there be of the projects?

Answer. We expect to award in late May a contract with an independent evaluator to examine a number of specific issues relevant to the program. The independent evaluation will focus its efforts on three major areas:

- o Monitoring of sites' progress in planning/implementing the components of their proposed projects. This will include conducting a series of case studies of a selected group of hospitals to examine and understand the factors contributing to the success or failure of particular projects.

- o Evaluating the overall success of the grant program in achieving the goals as set forth in the legislation.

- o Developing appropriate recommendations for inclusion in the mandated report to Congress and lessons learned for sharing with rural hospitals.

RURAL HOSPITAL TRANSITION GRANSTS

Question. How do you plan to disseminate information to rural hospitals about what works?

Answer. Based on the case study results and overall evaluation findings, the independent evaluator will be asked to develop a "guide" of lessons learned under the grant program which can then be shared with rural hospitals.

Question. The Administration requested no funds for the Rural Hospital Transition Grants in FY 1990. Do you think that one year of funding is sufficient to meet the need?

Answer. We believe that by awarding grant funds for the maximum period authorized under the legislation (24 months), we will have sufficient time to evaluate the success in planning and/or implementing the

programs proposed by the hospitals to better address the health care needs of the Medicare patients they serve.

Question. Does the Medicare trust fund have enough in it to spare the $15 million authorized for this program?

Answer. We believe that the funding appropriated in fiscal year 1989 to conduct this program is sufficient to implement and evaluate the success of implementing the grant program. The assessment process which each hospital conducted in developing an application for grant funding under this program probably furthered its understanding of the nature of the health care delivery problems it faces and the potential ways to address those problems.

On the issue whether greater funds are available, the Hospital Insurance (HI) Trust Fund balance was about $66 billion at the beginning of the FY 1989. That balance, however, is expected to fall to zero shortly after the turn of the century. Any added outlays must be weighed against future health care for all older Americans, not just against the current accounting balance of the HI Trust Fund.

PRO REVIEWS OF RURAL HOSPITALS

Congress mandated that Peer Review Organizations' evaluations of rural health providers take into account the specific problems with delivering care in rural areas. For instance, if a patient would have to travel back and forth 60 miles to get to the hospital for a test two days in a row, it's proper to keep her in overnight. The PRO reforms also mandated that PRO reviewers of rural practitioners should be people who practice in a similar setting --- the real meaning of peer review.

Question. What's been done to implement these improvements?

Answer. We believe that the PROs, based upon our earlier instructions, already take into account "social norms" when they make determinations.

We are in the process of identifying other types of cases that would be allowable under this provision. In doing this analysis, we have consulted with our Office of General Counsel and have sought input from the American Association of Retired Persons.

Once the types of situations are outlined, we will issue instructions to the PROs outlining what new actions need be taken.

Question. Is HCFA monitoring the use of rural reviewers?

Answer. In order to obtain a PRO contract, organizations must agree to use physician reviewers who practice in a comparable setting to the physician rendering the care under review, where possible.

HCFA does not routinely monitor PRO use of rural physician reviewers; however, we evaluate the performance of PROs in reviewing care rendered in a rural setting as discussed below.

HCFA monitors PRO performance through the Peer Review Organization Monitoring Protocol and Tracking System (PROMPTS). The PROMPTS being used to evaluate PROs include the re-review of samples of PRO decisions by HCFA regional offices. The regional office staff performing the re-reviews are familiar with the unique nature of rural practice. If problems are found, the PROs are requested to submit a corrective action plan. The results of the regional office's review are used in arriving at decisions on the renewal of PRO contracts.

PRO REVIEWS OF RURAL HOSPITALS

Question. Are the numbers of rural reviewers increasing?

Answer. Since we have no data about the actual number of rural PRO physician reviewers, we do not know if the number is increasing. Likewise, we have no data to indicate that the number is insufficient or decreasing.

We have had no complaints from physicians or hospitals about the lack of PRO physician reviewers who practice in settings similar to the physician whose services are being reviewed.

Question. What proportion of PRO reviewers have rural practice experience?

Answer. We do not have data about the experience of physician reviewers employed by the PROs.

Question. How many rural doctors have been recruited as rural reviewers?

Answer. We do not collect data about the number of rural physician reviewers employed by the PROs. Absent evidence to the contrary, we have no reason to believe that the numbers are insufficient.

AUTOMATION COSTS

On your schedule reflecting your automation costs, you indicate that you will require about $22 million in fiscal year 1990 for headquarters automation systems as a result of the passage of the Catastrophic Insurance Act.

Question. Please provide details on what these funds will be used for.

Answer. The FY 1990 request for $22 million to implement Catastrophic Health Insurance includes the acquisition of a variety of ADP hardware, services, and data communications lines. In the hardware/package software area, HCFA has projected $10,960,000 for the following:

o Mainframe computer upgrade	$3,680,000
o Front-end processor	750,000
o On-line storage	2,500,000
o Near-line storage	1,315,000
o High-speed printers	900,000
o Data communications equipment and software	400,000
o Package software	1,415,000

In the services area, HCFA has projected $8,075,000 for the following:

o Software design and development	2,600,000
o Software maintenance and enhancements	500,000
o Acquisition support expertise	440,000
o Data administration support	1,000,000
o Data administration training	135,000
o Facilities management	1,400,000
o Hardware maintenance support	2,000,000

Finally, $2,965,000 will be needed to fund high-speed data communications linking the HCFA Data Center, Medicare contractors, Common Working File (CWF) sites, and the Prescription Drug Claims processors (which will be testing for implementation in FY 1991).

Question. Are there any operations that these funds will be used for which support other administrative activities, such as supporting Medicare operations in shared data processing for other operations?

Answer. The $22 million will support several administration activities which we consider critical to the success of the CHI implementation -- specifically the transfer of the Health Insurance/Supplementary Medical Insurance (HI/SMI) System and the data communications between the Common Working File (CWF) sites and the HCFA Data Center (HDC). The transfer of certain Medicare-related ADP operations from SSA's National Computer Center to the HDC establishes at the HDC a consolidated point under HCFA's control for storing and maintaining records on Medicare beneficiary entitlement, enrollment, utilization, and liability. This control will facilitate the management of changes required by the CHI legislation.

Also, as part of the transfer, a consolidated, nationwide Medicare data communications host will be established at the HDC. Establishment of a single, HCFA-controlled point for records maintenance and hosting of data communications will promote smooth data flow between HCFA and Medicare processing sites (carriers, intermediaries, Common Working File contractors, and Prescription Drug claims processors).

A third benefit, related to HCFA's general data management as well as CHI, is that the transfer will also ensure that data used for program management, statistical, and actuarial purposes (90 percent of which come in through the HI/SMI system) are consistent, accurate, and timely. With the ongoing implementation of CWF and the phasing out of extensive data communication between the HDC and Medicare contractors, we have projected a decrease in data communications costs of over $.5 million in FY 1991.

Question. Please explain if this funding process has any offset in the Trust Fund operations.

Answer. There will be no Trust Fund offset with respect to the transfer of the HI/SMI from SSA to HCFA in FY 1990. The transfer will begin in the middle of FY 1990 and there will be a period of parallel processing. SSA and HCFA are discussing possible out-year offsets.

INFORMATION RESOURCE MANAGEMENT

Presently there is no administration-wide information resource management plan which includes total overview of Medicare, Medicaid, and headquarters

ADP activities. Also, the administration's senior information resource management official does not have authority over non-headquarters Medicaid and Medicare ADP activities.

Question. Because of the above situation, do you believe that the administration may miss opportunities to develop more effective and efficient use of ADP resources in support of total HCFA mission? For example, are there opportunities for consolidating systems or information processing if the senior information resource official had a broader overview of and responsibility for all the administration's information resource activity?

Answer. It is true that HCFA's senior IRM official does not exercise direct authority over non-headquarters Medicaid and Medicare ADP activities. The Associate Administrator for Operations (AAO) oversees those operations as well as those of the Peer Review Organizations (PROs). HCFA's approach to the complex operational environment of Medicare and Medicaid is to integrate all aspects of their management rather than focus on a single function (ADP). With this division of responsibilities, HCFA has effectively minimized overlapping systems and information processing among its external agents. Further, the AAO has shared information which affects headquarters ADP activities with the senior IRM official.

One example of HCFA's success in consolidating information systems of its agents is that initial estimates for PRO annual ADP costs were in excess of $100 million. After further analysis, HCFA directed the PROs to process data collected by Medicare contractors rather than undertake a second data collection effort which resulted in actual ADP costs for the PROs of less than ten percent of the original estimate. The AAO and senior IRM official have worked together on projects to simplify and/or provide more consistent information, such as the Uniform Bill Project. Also the AAO is currently evaluating shared claims processing and maintenance arrangements between Medicare contractors which could result in 3-year savings of over $100 million.

The senior IRM official is currently responsible for the implementation of the Project to Redesign Information Systems Management (PRISM). AAO staff have been directly involved in that effort from its inception. In turn, staff of the senior IRM official have been involved in every project initiated by the AAO which will affect headquarters ADP operation, such as the implementation of Catastrophic Health Insurance and the Common Working File (CWF). The senior IRM official has directed HCFA's systems integration contractor to provide her with an overview of all of these external efforts describing the interfaces, critical tasks, and effects on the PRISM timeline.

MEDICAID SAVINGS

The General Accounting Office estimates $500 million could be recovered from estates of deceased nursing home patients, to offset increases needed in Medicaid appropriations. Since you estimate Medicaid funding at $37.4 billion in fiscal 1990, an increase of $3.1 billion, any savings that could be achieved would obviously help reduce the deficit.

Question. Have you examined this GAO report, to see if further Medicaid savings can be achieved without adversely affecting surviving spouses?

Answer. We have examined the report and concur with the GAO's findings that the savings would be achievable if each State would institute an effective estate recovery program. Current law allows, and the GAO recommends, recovery from the estate only upon the death of the surviving spouse.

Question. What actions can the Health Care Financing Administration take, under current law, to help States design more effective estate recovery programs?

Answer. HCFA has undertaken an extensive marketing campaign in the third party liability (TPL) arena. As part of that effort, HCFA is heavily involved in promoting estate recoveries. Since these recoveries are optional, we speak to State decision makers about instituting such programs in their States. This usually involves State legislation; thus, we market estate recoveries to State legislators, governors' staffs, budget officers, and single State agency heads.

Once a State has decided it is interested in the program, we refer it to a State which already has a good program (e.g., Oregon or California). Our position has always been that we can best serve by providing general information and then referring States to another State with an effective program for detailed information. Our State Agency Guide to Successful Practices contains a section on estate recoveries, and we reference this practice each time we address a group or market directly to a State.

CONVENTIONAL EYE WEAR

Following cataract surgery and the implant of an intraocular lens, some patients still need conventional eyeglasses to restore their vision. The Health and Human Services Inspector General estimated the costs of conventional eye wear on behalf of these patients at $72 million in 1986. Under current Medicare law, coverage of routine eye care and conventional eyeglass should be excluded.

In recent years, the GAO and the Health and Human Services Inspector General recommended that the Health Care Financing Administration exclude from coverage, conventional eye wear for beneficiaries following cataract surgery. These eye wear corrections should be considered routine eye care not covered by the Medicare program.

Question. What action, if any, has HCFA taken to review this issue further?

Answer. We have reservations about proceeding at this time with plans to withdraw Medicare coverage of conventional eyeglasses in these cases. Some of these patients cannot have their vision fully restored to pre-operative readings without wearing conventional eyeglasses as well. We are committed to reviewing the issue further but have no immediate plans for regulatory changes.

DIALYSIS RATES

The Health Care Financing Administration sets reimbursement rates for outpatient dialysis treatment by combining independent and hospital facilities costs. Hospital rates are adjusted upward to recognize their higher costs. However, downward adjustments are not made to the rates of independent facilities to recognize their lower costs of providing services. Separate rates for providing outpatient dialysis services need to be established to more properly reflect the costs of providing these services in different environments.

I understand that the costs of providing outpatient dialysis services varies greatly depending on whether it is provided in a hospital or in an independent facility. However, the rate reimbursed by HCFA for this service is set by combining independent and hospital facilities cost.

Question. What is the rationale for establishing a reimbursement rate for outpatient dialysis using hospital and independent facilities' costs? For keeping the combined rate?

Answer. Section 1881(b)(7) of the Social Security Act established the basis for the current payment methodology. The statute requires payment rates that differentiate between hospital-based and independent renal facilities and which will more effectively encourage the more efficient delivery of dialysis services and provide greater incentives for increased use of home dialysis. Data from hospitals and independent facilities were used in setting a payment

rate. To account for their higher costs, hospitals were provided an overhead add-on and a five percent adjustment to their payment rate. These adjustments resulted in hospital-based renal facilities being paid on average $4.00 more per treatment than independent facilities.

Question. Shouldn't the rates reimbursed by Medicare for outpatient dialysis be uncoupled?

Answer. The statute requires the Secretary to promote the more efficient delivery of dialysis services. Establishing payment rates based on the separate costs of independent and hospital renal facilities might not promote efficiency. The fact that hospitals report higher costs is not a reason to uncouple the rates. However, to the extent that hospitals have an atypical patient mix or are located in an isolated geographical area, a differential in payment rates is permitted under the End Stage Renal Disease exception process.

MEDIGAP INSURANCE

About 40 percent of the 2,000,000 Medicaid beneficiaries in nursing homes continue to pay for Medigap insurance. Payments for Medigap insurance reduce amounts available to cover the costs of nursing home care. Because almost all medical bills of nursing home patients over age 65 are already covered by Medicare or Medicaid; the purchase of Medigap insurance, in effect, increases the cost of nursing home care to both State and Federal governments. Federal savings by not allowing medical deductions for Medigap insurance for Medicaid nursing home residents, roughly estimated at $120 to $180 million.

Question. I understand that many Medicaid beneficiaries receiving nursing home benefits continue to purchase Medigap (supplemental health) insurance. To what extent do Medicaid nursing home patients over age 65 need this kind of insurance, since almost all of the medical expenses are covered?

Answer. Since Medicaid is the payer of last resort when an insurance policy is in effect, it may be cost beneficial to a State to pay the premium to continue a Medigap policy on the patient's behalf, or to allow the premium payment as a deduction to countable income. The question for the Medicaid program is whether the Medicaid program benefits more from the Medigap policy being in force, or whether the premiums (deduction from countable income) cost more than the Medicaid program savings resulting from the coverage. The answer depends on the State program in question, and the health needs of the patient.

Question. Has HCFA ever computed the benefit-cost ratio of allowing individuals to continue purchasing Medigap (supplemental health) insurance.

Answer. No. There is no single benefit-cost ratio to compute. As explained in the previous answer, the benefit-cost ratio is dependent upon the premium amount, the specific services covered by the insurance, the specific services covered (and payment schedule) in the State in question, and the health needs of the recipient. We have always urged States to compute their own benefit-cost ratios. However, there is no current authority for a State to mandate that an individual drop an insurance policy nor to not allow the deduction from countable income.

INPATIENT PSYCHIATRIC CARE

Medicare limits inpatient care in psychiatric hospitals to 190 days during a beneficiary's lifetime. Over time, more and more inpatient psychiatric care has been provided in general hospitals rather than psychiatric hospitals; however, the 190 day limit has not been extended to the more costly care provided in general hospitals. Furthermore, recent changes authorized by the Medicare Catastrophic Coverage Act, in effect, eliminate the 60 day limit on care provided in a general hospital. As such, psychiatric patients can now receive 365 days of care in the psychiatric wing of a general hospital. The 190 day limit does not apply to care provided in a general hospital.

Question. Have lifetime limits for inpatient psychiatric care in non psychiatric hospitals been analyzed recently? With what results?

Answer. Under current law, the 190-day lifetime limit on Medicare coverage of inpatient psychiatric services applies only to psychiatric hospitals. This limit is not imposed on inpatient psychiatric care provided in non-psychiatric hospital settings. The 190-day limitation was applied only to psychiatric hospitals because, at the time of the original Medicare legislation, inpatient psychiatric care was rendered for the most part, in State psychiatric hospitals. And long term care of the chronic mentally ill in State hospitals was generally considered the responsibility of State governments.

In February 1988, the Office of the Inspector General released its report on the Medicare Part A lifetime limitation on psychiatric hospital care and its effectiveness in controlling the utilization of inpatient psychiatric services. Their data showed that the 190-day lifetime inpatient treatment limit should be replaced because the patterns of practice in psychiatric care have changed, and because it is possible to save program dollars by substituting an

annual 60-day limit. The 60-day limit would apply to psychiatric hospitals and non-psychiatric hospitals.

While we agree with the Inspector General's conclusions that our current mental health regulations should be reviewed, we believe that we need more information on patterns of practice and on the effects on beneficiaries before we will be ready to make a policy recommendation. Also, we need to wait for final implementation of the OBRA 1987 mental health requirements before reevaluating the need for change in the inpatient psychiatric limit.

INPATIENT PSYCHIATRIC CARE

Question. With excess capacity in many general hospitals, do you see a potential for abuse in the amount of inpatient psychiatric care provided by these facilities?

Answer. We have no evidence that this is happening. We believe physicians will continue to screen patients for their need for inpatient psychiatric care and will not order admissions which are not needed. PROs will also protect against misutilization by identifying inappropriate patterns of utilization and denying medically unnecessary care.

OVERPAYMENTS TO HMOs

In March 1989, GAO issued a report critical of your agency's oversight of Medicare health maintenance organizations (HMOs). GAO concludes that millions of dollars of overpayments resulted from failure of the Health Care Financing Administration to monitor Medicare HMOs. Your response to GAO, in part, cited "limited travel fund and workload consideration" as reasons for not conducting sufficient on-site reviews.

Question. Does your fiscal 1990 budget permit more thorough monitoring visits of HMOs?

Answer. The GAO report dealt with adjusted community rate (ACR) proposals submitted to HCFA's Office of Prepaid Health Care (OPHC) by health maintenance organizations (HMOs) and competitive medical plans (CMPs) with Medicare contracts. HMOs and CMPs with Medicare risk contracts are required to submit ACR proposals to justify their planned Medicare benefit offerings and the premiums they plan to charge Medicare members. The GAO report stated that HCFA's ACR review process - at that time consisting of a desk review to grant prior approval of premiums and benefits, and occasional after-the-fact on-site monitoring reviews - was insufficient oversight of the ACR process. Had there been greater oversight, the

"overpayments" identified by GAO might not have occurred. (Under current law, there are no overpayments as such to risk contractors; there is no authority to make retrospective adjustments of prospective capitation payments made to risk contractors.)

What GAO identified were instances where GAO felt that a greater portion of the Government's payment to contracting HMOs/CMPs should have gone towards the provision of additional benefits (not covered under traditional Medicare) or towards a reduction in premiums that the HMOs/CMPs were permitted to charge members to recoup amounts that are beneficiary liabilities in traditional fee-for-service Medicare.)

Our fiscal 1990 budget does permit additional oversight of HMO/CMP ACR submissions as recommended by GAO. More intensive monitoring of accounting activities related to the ACR process will be incorporated into the current OPHC routine biennial on-site monitoring visits for all plans with Medicare risk contracts. If a problem is detected involving the ACR, a monitoring site visit will be scheduled outside of the normal routine monitoring cycle. The protocol to be used as the basis of such monitoring site visits has been significantly expanded to permit a thorough review of ACR accounting procedures.

OVERPAYMENTS TO HMOs

Question. What further comments do you have about this GAO report?

Answer. In addition to the Department's comments that have been made a part of the GAO report, we would like to comment that HCFA now requires that each ACR submission be accompanied by a statement from an HMO/CMP officer or other responsible person certifying the accuracy and reasonableness of the submission. HCFA now requires that all ACR submissions be sent in automated (personal computer) format to permit faster analysis and comparison with a database of ACR data being continually updated by HCFA.

HCFA is considering the feasibility of recouping excess HMO/CMP payments which may result from the use of inaccurate or incomplete ACR data (an action that would require a legislative change).

Finally, we would note that, although risk contractors do not incur "overpayments" which the Department has the right to recoup, HMOs and CMPs with cost-reimbursed contracts can incur overpayments. During fiscal year 1989, HCFA has collected approximately $24 million in overpayments and an additional $450,000 in interest charges from cost contractors for prior contract periods.

HEARINGS AND RECONSIDERATIONS

Question. We note that the budget justification proposes reducing Medicare contractor funding for hearings and reconsiderations by almost one-fourth, or $15.7 million. What reason is there to believe that a reduction of this magnitude in the hearings and reconsiderations workload will occur?

Answer. The budget request of $53.4 million is a reduction of $15.7 million from FY 1989 expenditures but contains sufficient funds to cover the impact of OBRA. It also recognizes a significant drop in Part A appeals over the past few months. For example, in FY 1988 contractors received about 62,000 appeals; in FY 1989 we expect they will receive about 33,000 appeals and will reduce the backlog of 30,000 at the beginning of FY 1989 to about 2,500 by the year's end. The FY 1990 level of effort will therefore be about one-half that of FY 1989. Part B appeals are expected to remain about the same for FY 1990 as they were for FY 1989.

INCENTIVES TO MEDICARE CONTRACTORS

Concerning the incentive payments to carriers that demonstrate success in increasing the number of participating providers in the service area that were mandated in the OBRA of 1986,

Question. What criteria has HCFA established for awarding these payments?

Answer. For the purpose of determining each carrier's eligibility for an incentive payment, we make two comparisons. We compare the carrier's physician participation rate after the latest enrollment period with its participation rate after the prior enrollment period. A similar comparison is made with the proportion of covered charges for services of participating physicians during the quarter following the latest enrollment period with those of the quarter following the prior enrollment period.

The difference which yields the higher percentage increase is used for the purpose of determining eligibility for award of the incentive payment. We intend to pay incentive bonuses for fiscal year 1989 and fiscal year 1990 to any carrier that achieves an increase of at least one tenth of one percent in the number of participating physicians or to carriers with a similar increase in total payments for participating physicians services.

Question. What incentive payments have been made to carriers for fiscal years 1986-88?

Answer. The Omnibus Budget Reconciliation Act of 1987 required HCFA to make the first incentive payment in FY 1988. Payments to carriers in FY 1988 amounted to $4,284,900.

Question. How many carriers have received incentive payments for fiscal years 1986-88?

Answer. The incentive payments made in FY 1988 were made to 39 carriers for increasing participating physician participation.

Question. What information has HCFA developed regarding specific carrier strategies and practices that have been successful in increasing the number of participating providers?

Answer. HCFA has not developed an information data base regarding specific carrier strategies and practices that have been successful in increasing the number of participating physicians. Each carrier uses various strategies ranging from provider education to an increased number of professional relations representatives to increase participation. The decision of which strategies to use is left to each individual carrier. An informal survey by HCFA of carrier strategies is planned for the future.

SECTION 223 OF CATASTROPHIC COVERAGE ACT

Question. What plans has HCFA developed for implementing the requirement of Section 223 of the Medicare Catastrophic Coverage Act regarding placing a notice on each Explanation of Medicare Benefits offering assistance in locating a participating physician or supplier?

Answer. Carriers programmed the changes to the Explanation of Medicare Benefits and have been issuing the revised statements since the beginning of 1989.

Question. What plans has HCFA developed for implementing the requirement of Section 223 of the Medicare Catastrophic Coverage Act regarding mailing of annual notices to beneficiaries explaining the coverage and limitations of the Medicare program, the deductibles and coinsurance payments required under the program and the limited coverage Medicare provides for nursing home care?

Answer. In addition to mailing a 16-page explanation of the Catastrophic Coverage Act to all Medicare enrollees, HCFA has mailed a completely revised 1989 Medicare Handbook to each beneficiary. The

Handbook contains a detailed description of the Catastrophic provisions as well as explanations of existing Medicare coverage, coverage limitations, deductibles and coinsurance amounts, information on participating physicians, claims filing, appeal rights, and where to get additional information or assistance. All 32 million beneficiaries will receive copies of the 1990 Medicare Handbook as well. Total FY 1989 budget allocation for these activities is approximately $14.7 million.

Of course, all beneficiaries will continue to receive, at least annually, Medicare check stuffers or flyers containing updating information on premiums, deductibles, coinsurance, and other special announcements of program changes.

SECTION 223 OF CATASTROPHIC COVERAGE ACT

Question. What funding has HCFA allocated for these activities?

Answer. HCFA's FY 1990 budget request includes $15.0 million for these activities.

GAO STUDY

Last year, at the request of the Committee, GAO compared carrier and intermediary performance and found that claims processing times improved for the first time since fiscal year 1983.

Question. Did this improvement continue during fiscal year 1988?

Answer. Medicare contractor average processing times improved until the April-June 1988 quarter. Since then they have steadily increased. This increase is a result of the required payment floors, not a decline in performance. During the July-September 1988 quarter no claim could be paid before the 11th day following receipt. Beginning October 1, 1988, no claim could be paid before the 15th day following receipt.

The table below illustrates:

Period	Intermediary Days	Carrier Days
July - September 1987	11.3	14.6
October - December 1987	9.8	12.9
January - March 1988	10.1	13.6
April - June 1988	9.2	12.3

Period	Intermediary Days	Carrier Days
July - September 1988	13.8	15.5
October - December 1988	17.1	17.5
January - March 1989	17.9	19.2

The Committee also asked GAO to determine the timeliness of processing for deceased beneficiary claims. GAO reported that there were delays in processing such claims but that HCFA planned to issue new instructions to its carriers in July 1988 which would facilitate processing such claims.

GAO STUDY

Question. Has HCFA issued these new instructions?

Answer. Instructions to implement the simplified procedures for processing deceased beneficiary claims were released to the contractors on April 5, 1989.

UTILIZATION REVIEW

Dr. Roper previously testified that a large portion of the tremendous growth in part B costs was related to increases in the number of services provided. He stated that HCFA's short-term remedy to deter these service increases would rely upon increased utilization review.

Question. Does the FY 1990 budget signal a departure from this plan?

Answer. HCFA believes that functions which are legislatively mandated, or which have legislatively mandated timeframes, must be fully funded. These functions include claims payment, hearings, and the participating physician program. Also, we believe it is necessary to fully fund all functions associated with the implementation of catastrophic health insurance, including beneficiary services, where we expect a greatly increased volume of inquiries. The reductions, therefore, had to be allocated to areas where there is some discretion. Accordingly, we allocated the reductions to payment safeguards and productivity investments.

A high quality Medicare administrative system is critical to our efforts to control excessive Medicare cost increases. Medicare contractors are responsible for assuring timely services to beneficiaries and health care providers. It is critical that contractors also protect the Medicare trust funds from improper and excessive claims -- the so-called payment safeguard and audit activities.

The FY 1990 Reagan budget included a six percent increase in funding for Medicare contractors. As you know, the Bush budget includes the Health Care Financing Administrations's Program Management appropriation which contains funds for contractor costs in the residual freeze category. Medicare contractor utilization reviews may warrant an alternative funding mix with these totals.

The level of funding for payment safeguard and utilization review functions does not exclusively determine the quality of the contractor system or the amount of Medicare savings. Each of the 88 Medicare contractors report different returns on payment safeguard and audit activities. Allocating appropriated funds to high-return activities and eliminating conflict of interest situations (such as those highlighted in recent news reports) can control abuse. With the release of FY 1989 contingency funds, Secretary Sullivan has recently embarked on a major initiative in this area.

UTILIZATION REVIEW

Question. How does HCFA plan to address volume increases?

Answer. During the period 1977 through 1987, Medicare spending for physicians' services increased at annual compound rates of 16 percent. Over the next 10 years, even without any program expansions, Medicare spending for physicians' services will likely triple.

Several factors contribute to the explosive growth in spending of the past decade. About 15 percent of the growth may be attributed to the increase in the number of beneficiaries enrolling in Medicare. About 40 percent is due to the price increases resulting from inflation. The remaining 45 percent is due to increases in the volume and intensity of services being provided.

Previous efforts to control volume, such as utilization review, peer review, and reductions in payments have been dwarfed by the immensity of the volume problem. While HCFA believes these efforts are useful and should continue, HCFA recognizes that a system wide approach to controlling volume, such as an expenditure target, is necessary.

An expenditure target sets a socially acceptable rate of increase in physician spending. Future physician fee updates would be adjusted based on the previous year's experience in meeting the target. An expenditure target does not ration care. It is simply a pricing mechanism that would adjust payment updates in order to control volume. Payments would not be capped or stopped during any given year.

HCFA believes an expenditure target will complement its current utilization control efforts. In addition, HCFA continues to support the Department's "effectiveness" initiative which is providing information on "what works" in the practice of medicine. From this work, physicians will be able to base treatment decisions on empirical data on appropriate care. HCFA also continues to promote the private health plan option as providing a competitive approach to the delivery of health care services.

MEDICARE CONTRACTORS/PROFESSIONAL RELATIONS

We note that the budget justification proposes reducing Medicare contractor funding for professional relations by $1.5 million or about 17 percent.

Question. What professional relations functions and activities do you propose to curtail or suspend to achieve this reduction?

Answer. There are five major initiatives for which professional relations funds are currently budgeted: 1. Providing physicians and suppliers with adequate advance notice of policy and procedure changes; 2. providing timely and accurate responses to participant inquiries about coverage, reimbursement and claim status; 3. Making an Ombudsman available to resolve processing issues not resolvable through normal procedures; 4. Conducting workshops for physician and supplier office staffs; and 5. Supplying speakers at meetings of medical societies and other provider groups. All of these initiatives will be continued but at reduced levels of effort.

MEDICARE PARTICIPATING PROVIDERS

Question. What results have the Medicare Participating Provider and Supplier Program (MPPSP) achieved? In particular, what changes have taken place in the number and percentage of participating providers, and in the proportion of Medicare claims submitted by participating providers?

Answer. The following table shows the percentage of physicians and suppliers who are participating providers:

	May 1986	January 1987	April 1988	January 1989
Phys	28.3%	30.6%	37.3%	40.7%
Supps	19.0%	18.6%	20.3%	21.0%

The proportion of Medicare claims submitted by participating providers has grown from 37.9 percent in

FY 1985 to 50.0 percent in FY 1988. Data from the first quarter of FY 1989 shows the rate at 53.8 percent.

Question. We note that the budget justification proposes a reduction in Medicare contractor funding for MPPSP activities of $4.9 million or about 17 percent. What MPPSP functions and activities do you propose to curtail or suspend to achieve this reduction?

Answer. Initially, the reduction of $4.9 million was going to result in the elimination of the carrier incentive payments for increasing participation in the Medicare participating physician program. We had planned to submit a legislative proposal to eliminate the requirement to pay the incentive bonus. Upon subsequent review we decided to retain the bonus program and take the $4.9 million cut with a minor adjustment to claims processing unit costs.

SOCIAL SECURITY ADMINISTRATION

STATEMENT OF DORCAS R. HARDY, COMMISSIONER

ACCOMPANIED BY:

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET
JOHN R. DYER, DEPUTY COMMISSIONER FOR MANAGEMENT
LOUIS ENOFF, DEPUTY COMMISSIONER FOR PROGRAMS

OPENING REMARKS

Senator BUMPERS [presiding]. The subcommittee will come to order. Senator Harkin will rejoin us momentarily, but I am going to go ahead and open the meeting.

The next witness is the Social Security Commissioner, Dorcas Hardy. The operation of the Social Security system involves paying over $200 billion a year in benefits to 38 million beneficiaries and tracking the earnings of 130 million workers.

To accomplish this the Social Security Administration has over 1,300 field offices and about 65,000 employees. Ms. Hardy has presided over a tumultuous period in the history of the Social Security Administration taking on the enormous and complex task of computer modernization as well as the unpopular downsizing task which has already resulted in a 20-percent reduction in the staff.

This hearing will examine some of the problems associated with these changes and the impact on the services to the elderly and the disabled. Although you have sometimes been at odds with Members of Congress, I know we share a common goal—these are Senator Harkin's goals. I do not know whether we are at odds yet or not. We are here to find out.

PREPARED STATEMENT

Although you have sometimes been at odds with Members of Congress, I know we share a common goal to better serve the American public, and your dedication and hard work are appreciated.

Commissioner Hardy, if you would briefly summarize your budget requests, we can get to questions more quickly. Your entire prepared statement will be included in the record.

[The statement follows:]

STATEMENT OF DORCAS R. HARDY

Mr. Chairman and members of the Committee, I am pleased to be here today to present the fiscal year 1990 appropriation requests of the Social Security Administration (SSA). As you know, the Bush Administration submitted its fiscal year 1990 budget to Congress on February 9. This budget specifies many Administration priorities, including full funding of Social Security benefits, Supplemental Security Income benefits, and Special Benefits for Disabled Coal Miners. The Bush budget also proposes holding aggregate spending for many Federal programs at the fiscal year 1989 level. Spending for individual programs in this residual category is to be negotiated with Congress. Social Security Administration administrative expenses are included in this residual category. For the purpose of beginning the negotiating process, the Administration is presenting the funding requests included in the Reagan budget for these residual programs. As such, the following testimony presents the Reagan budget requests for the programs in the residual category (Limitation on Administrative Expenses) and the Bush budget requests for programs outside the residual category. These requests total $16.9 billion in budget authority and reflect our commitment to provide quality service to over 40 million beneficiaries, through the efforts of a stable and dedicated workforce using the tools of modern technology.

Summary of Budget Requests Before the Committee

I would like to summarize the SSA appropriation requests before the Committee:

- $192.0 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to Federal funds.

- $859.9 million for Special Benefits for Disabled Coal Miners. These funds cover benefit payments and administrative expenses for that portion of the black lung program administered by SSA.

- $12.1 billion for the Supplemental Security Income (SSI) program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.

- $3.8 billion for the Limitation on Administrative Expenses. This request provides resources needed to administer the old-age and survivors and disability insurance programs and to perform certain administrative functions for the Medicare program. It also includes resources to administer the SSI program and for combined annual wage reporting for Social Security and Internal Revenue Service purposes. The trust funds are reimbursed from the general fund for the administrative costs of the SSI program and for the nontrust fund share of annual wage reporting. The LAE account includes about $2.8 billion for regular salaries and expenses, $750 million for State Disability Determination Services, $203 million for automated data processing and telecommunications expenses, and a contingency reserve of $48 million.

Strategic Plan and Agency Priorities

The SSA Strategic Plan has guided development of SSA's fiscal year 1990 budget request. The Strategic Plan and the budget reflect the Agency mission to "administer equitably, effectively and efficiently, a national program of social insurance as prescribed by legislation." SSA's mission is met through six operating priorities:

- Maintaining the fiscal integrity of the Social Security trust funds.
- Providing the best possible service to the public.
- Improving management of SSA programs.
- Improving public confidence in Social Security.
- Using the best and most appropriate technology available to administer SSA programs.
- Ensuring that SSA can count on a properly skilled and highly motivated workforce.

SSA's budget addresses these priorities by providing adequate resources to continue accurate and timely processing of SSA's workloads, and by supporting some Strategic Plan initiatives. At the same time, the budget projects continued gradual employment reductions through attrition, as the Agency realizes the benefits from investments in technological and management improvements.

Service to the Public

One of the Agency's highest priorities is to provide quality service to the public. Even with continuing program growth and declining staffing, we have been able to increase the speed and accuracy with which claims and other actions are processed and maintain high levels of client satisfaction with our service. Between 1984 and 1988, surveys by the General Accounting Office and the Office of Inspector General of the Department of Health and Human Services showed an increase in the percent of the public rating SSA service as "good to very good" from 78 percent to 87 percent. We are committed to maintaining quality service to our public.

SSA has achieved major improvements in productivity and service through management initiatives and by reducing or eliminating manual processes through the use of automated data processing and modernized telephone systems. Accordingly, an agency that once relied on a very large workforce, now has a smaller, more efficient workforce that relies increasingly on modern technology to deliver quality public service. SSA's recent service improvements include:

- Implementation of Toll-free "800" Number Telephone Service

  On October 1, 1988 this service was implemented for about 60 percent of the Nation--including those people who previously had to pay long distance charges to reach one of our local offices--and it is being phased in for the rest of the country during fiscal year 1989. The "800" number service dramatically improves the accessibility and convenience of SSA service by extending the hours for personal service from 7 a.m. to 7 p.m. and by providing answering equipment at night and on weekends and holidays, to provide general Social Security information and take messages for call-back on the next business day.

- Improved Earnings Statement Information Provided to Workers Upon Request

  In August 1988 SSA implemented the new "Personal Earnings and Benefit Estimate Statement," which provides workers with a more complete statement of their earnings and estimates of potential Social Security benefits, upon

request. It is intended to give workers a better understanding of their Social Security protection, which also may help them to do their own financial planning.

- Development of a Service that Allows Parents to Request Social Security Numbers for Their Newborn Children as Part of the State Birth Registration Process

  If a parent so chooses, the State provides birth registration information to SSA on magnetic tape, thereby saving time for the parents as well as for SSA in enumerating the children later. Based on the success of pilots in three States, a total of 36 States are now participating in this program, and six more will be participating by July 1989. We are working toward expanding this service virtually nationwide.

- Increased Options for Obtaining Social Security Service

  About half of SSA's claims are now taken over the phone, saving claimants time and money and avoiding unnecessary office visits. For those who prefer a face-to-face interview, that option is available; and all field offices offer appointments, which reduce waiting times and are more convenient to the public.

Partnership Between Systems and Service

Customer service is the guiding principle in all systems activities, with efforts concentrated on software development and implementation. A key element of SSA's systems modernization is implementation of the Modernized Claims System for Social Security claims.

More than 25,000 new terminals and related systems equipment have been installed in SSA's field offices and teleservice centers, linking them to the Modernized Claims System. Software now in use allows SSA staff to enter information directly into the system during the claims interview, gives immediate and accurate information on the status of claims development, and provides more data to employees for direct response to beneficiary inquiries. Future software releases will modernize the software for

eligibility and payment determinations, online benefit computations, and postentitlement actions. Effective utilization of this software will require increased computer capacity.

In addition to claims modernization and the service improvements previously noted, other recent systems accomplishments include:

- Completed posting the bulk of tax year 1987 annual wage reports by July 24, 1988, continuing a steady improvement in the Annual Wage Reporting process.
- Completed, by the end of January 1989, the automated process that credits beneficiaries for additional 1987 earnings. About 2.6 million beneficiaries received an average increase of $12.20 per month and average retroactive payments of $187 in their March 3, 1989 benefit checks.
- Initiated a new automated system to provide information on Social Security and SSI beneficiaries to State social services agencies. This system improves on the prior procedures for providing such information and reduces referrals to local SSA field offices.
- Implemented improvements to SSA's automated data interfaces with State vital statistics agencies to detect unreported beneficiary deaths.
- Made a number of improvements to automate manual actions and enhance operating efficiency of earnings record reviews, direct deposit procedures, returned check procedures, and administrative communications between field offices and processing centers.

SSA's computer systems are a key element of the Agency's service delivery system. SSA's ability to continue to provide quality service to the public depends upon adequate funding for automated data processing (ADP) and telecommunications activities, including ongoing maintenance of current systems as well as continued software improvements and hardware capacity increases. For this reason, SSA requests that the "cap" in fiscal year 1989

appropriation language which limits the amount of funding for ADP/telecommunications activities be lifted, and moreover, that our fiscal year 1990 appropriation contain no statutory earmarks or limitations. This would permit SSA to allocate more resources to ADP/telecommunications within the total amount available in the Limitation on Administrative Expenses.

Human Resources Management

SSA has been able to streamline its operations and continue gradual employment reductions due to management, procedural and automation improvements, which also enhance service to the public. From fiscal year 1984 to fiscal year 1988, SSA reduced its full-time equivalent (FTE) requirements by about 16 percent. Over the next 2 fiscal years, 1989 and 1990, we expect to reduce FTEs by another 5 percent, based on planned improvements and consistent with the goals and priorities of the Agency. Fiscal year 1990 represents the last year of a long-term plan to reduce SSA FTEs by about 17,000. All of these reductions will be accomplished through normal attrition, and our goal is to stabilize employment after this point, consistent with workloads and productivity.

SSA's appropriation requests support congressional and executive branch initiatives to restrain growth in Federal spending. Discretionary spending is tight, reflecting continuing productivity improvement and initiatives to reduce spending and find more efficient ways to process the Agency's work.

The resources requested for fiscal year 1990 are sufficient, and the flexibility to manage those resources will ensure that SSA is in the best position to continue initiatives to improve service and meet its vital national role.

Social Security Trust Funds

In closing, I would like to say a few words about the Social Security trust funds. Funds to pay benefits from the Old-Age and Survivors Insurance and Disability Insurance (OASDI) Trust Funds are permanently appropriated, and therefore are not part of the budget requests before this Committee. In

fiscal year 1990 we expect to make payments of about $217.7 billion to 35.4 million OASI beneficiaries, and payments of $23.5 billion to 4.1 million DI beneficiaries. The fiscal year 1990 budget shows steadily increasing balances in the OASI and DI trust funds, reflecting the continuing success of the bipartisan agreement reached on Social Security in 1983, which restored the financial integrity of the system into the next century. Under projections in the fiscal year 1990 budget, balances in the OASI and DI trust funds will grow to $229 billion by the end of fiscal year 1990.

Administrative expenses remain a small fraction of the overall trust fund operations. For fiscal year 1990, administrative expenses are estimated to be 0.8 percent of anticipated contribution income to the OASI and DI trust funds under current law and 1.0 percent of benefit payments.

Payments to Social Security Trust Funds

The fiscal year (FY) 1990 appropriation request for Payments to Social Security Trust Funds totals $191,968,000 and covers three general fund payments to the Social Security trust funds.

Beginning with FY 1988, we no longer request funds in this account to reimburse the trust funds for military service credits for current military personnel. These funds are being requested by the Department of Defense, Coast Guard, Public Health Service and National Oceanic and Atmospheric Administration so that the total costs related to current military and other uniformed service personnel are more accurately reflected in the budget.

Special Payments for Certain Uninsured Persons

The request before this committee includes $33,968,000 in FY 1990 to reimburse the Old-Age and Survivors Insurance Trust Fund for special benefits paid during FY 1988 to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These beneficiaries, a declining population, were not eligible for regular monthly Social Security benefits,

primarily because they retired before enactment of the Social Security Act or prior to coverage of their occupations under Social Security.

The FY 1990 request for Special Payments for Certain Uninsured Persons is $8,638,000 less than the FY 1989 appropriation. The population receiving special payments is a closed group of very aged persons which declines annually. As of September 30, 1988, 15,000 were receiving benefits chargeable to the general funds under this provision as compared to 20,000 a year earlier.

Reimbursement for Pension Reform Administrative Costs

Included in this request is a payment of $1,000,000 in FY 1990 to reimburse the Old-Age and Survivors Insurance Trust Fund for the general fund's share of the cost of administering pension reform responsibilities assigned to the Social Security Administration under P.L. 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors.

The request for FY 1990 reflects the ongoing level of activity for pension reform and the higher costs of automation. It is $25,000 less than the FY 1989 appropriation which contains funds for prior year adjustments and increases in the cost of automation. This level of funding will support 30 workyears in FY 1990.

Unnegotiated Checks

Also included in this request is a payment of $157,000,000 in FY 1990 to reimburse the trust funds for the value of benefit checks that remain uncashed after 6 months, plus interest. This payment is authorized by section 152 of the Social Security Amendments of 1983 (P.L. 98-21).

The request for FY 1990 is $107,000,000 higher than the FY 1989 appropriation to reflect a higher level of activity, and it includes funds for upward adjustments of prior year actual costs. Beginning in FY 1990, Social Security checks, like other Federal Government checks, will be negotiable for only 12 months from their date of issue under the provisions of the Competitive

Equality Banking Act of 1987 (P.L. 100-86). This law should sharply reduce, after FY 1990, the need for appropriations to reimburse the trust funds for the value of unnegotiated checks. After FY 1990, appropriations are needed to pay interest on the amount of unnegotiated checks. The value of unnegotiated checks will be credited directly to the trust funds from the Treasury Department's general fund when the checks are cancelled, pursuant to P.L. 100-86.

Special Benefits for Disabled Coal Miners

The fiscal year (FY) 1990 appropriation request for Special Benefits for Disabled Coal Miners totals $648,862,000 and is financed from general revenues. This is in addition to the $211,000,000 which Congress provided last year as a FY 1990 advance appropriation to fund first quarter benefit payments, which brings the total FY 1990 appropriation to $859,862,000. It includes $853,000,000 for FY 1990 benefit payments and $6,862,000 for administrative costs. The request also contains an advance appropriation of $215,000,000 for the first quarter of FY 1991. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that agency.

The year-to-year decrease in appropriation requests is due primarily to the continuing decline in the beneficiary population. The President's budget assumes benefit increases of 2 percent in January 1990 and 3 percent in January 1991, related to projected pay increases for Federal civilian employees.

Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows and certain other dependents of miners who were entitled to these benefits or whose deaths were due to this disease.

Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners benefits filed from December 30, 1969 through June 30, 1973 and claims for survivors benefits filed through December 21, 1973 or within 6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA pays benefits and maintains the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment of these claims and which budgets for the benefit payments and administrative costs of the program. Costs incurred by SSA in taking these claims are reimbursed by the Department of Labor.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come as a result of the death of miners and the death or remarriage of widows. At the midpoint of FY 1990, 220,000 beneficiaries will be receiving monthly benefits. This is a decrease of 17,000 from the 237,000 beneficiaries who will be receiving payments at the midpoint of FY 1989.

Explanation of Change

The FY 1990 request for benefit payments is $853,000,000--$25,656,000 less than the FY 1989 level.

The decrease in total benefits is due to a reduction of $56,000,000 for the lower number of black lung beneficiaries and a reduction of $2,000,000 for slightly lower average monthly payments for beneficiaries in current pay. This is partially offset by an increase of $24,000,000 which results from the effect of the January 1989 and January 1990 benefit increases of 4.1 percent and 2.0 percent respectively, and an increase of $8,343,523 which results from full use of unobligated balances during FY 1989.

Our budget request of $6,862,000 for FY 1990 black lung administrative expenses is $182,000 higher than the current estimate for FY 1989.

Advance Appropriation

The budget request includes an advance appropriation of $215,000,000 for the first quarter of FY 1991. This request ensures that benefit payments will continue without interruption into the next fiscal year.

Supplemental Security Income

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for fiscal year (FY) 1990 is $9,116,442,000 in addition to the $2,936,000,000 already appropriated for the first quarter of FY 1990, bringing the total appropriation to $12,052,442,000. This includes $10,925,613,000 for Federal benefits to aged, blind and disabled recipients; $13,739,000 for beneficiary rehabilitation services; $1,110,815,000 for payments to the trust funds for administrative costs; and $2,275,000 for research and demonstration projects.

We are requesting an advance appropriation of $3,157,000,000 for the first quarter of FY 1991 to ensure that beneficiaries will continue to receive benefits during the first quarter of FY 1991 in the event of a funding hiatus.

Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

The average monthly number of SSI recipients of Federal benefits is projected to increase 1.7 percent from 4,108,000 in FY 1989 to 4,177,000 in FY 1990, an increase of 69,000. This increase is due to projected growth in the number of blind and disabled SSI recipients, partially offset by a slight decrease in the projected number of aged SSI recipients.

The FY 1990 request for Federal benefit payments is $10,925,613,000 or $442,387,000 less than the FY 1989 level. The decrease is the net result of several factors:

--The FY 1990 request reflects 11 monthly payments compared to 12 monthly payments in FY 1989. The reduction in the number of payments is the principal reason for the reduction in the amount requested.

--SSA anticipates ending FY 1989 with an unobligated balance of funds which the budget assumes it will use in FY 1990.

--The decrease is partially offset by:

- o the 3.6 percent cost-of-living increase projected for January 1, 1990;
- o the projected increase in the number of blind and disabled SSI recipients.

Beneficiary Rehabilitation Services

SSA provides funds to reimburse vocational rehabilitation agencies for cost beneficial rehabilitations of SSI recipients and for instances of discontinuation of benefits prior to completion of vocational rehabilitation. For FY 1990 we are requesting $13,739,000 for this activity. This includes $11,200,000 for vocational rehabilitation and $2,539,000 for the referral of SSI recipients with drug or alcohol dependency to treatment programs and monitoring their participation in those programs.

Payments to the Trust Funds for Administrative Costs

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses account. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system, which has been audited by the

General Accounting Office, to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1990 request for this activity is $1,110,815,000.

Research and Demonstration Projects

This activity funds title II and title XVI research and demonstration projects authorized by sections 1110 and 1115 of the Social Security Act. SSA plans to continue its new approach to demonstration and research activity, concentrating on assisting beneficiaries to secure employment. The FY 1990 request for this activity is $2,275,000.

Advance Appropriation

The budget request includes an advance appropriation of $3,157,000,000 for the first quarter of FY 1991. This request insures that benefit payments will continue without interruption into the next fiscal year.

Limitation on Administrative Expenses

The Limitation on Administrative Expenses is included in the Bush budget residual category. As such it is subject to negotiations with Congress. However, for purposes of starting the negotiation process, we are presenting the Reagan budget request.

The Limitation on Administrative Expenses is a request for authority to spend up to $3,833,389,000 in fiscal year (FY) 1990 from the trust funds for administrative expenses of the Social Security Administration (SSA). From this account, SSA pays for administration of the old-age and survivors and disability insurance programs, the supplemental security income (SSI) program for the aged, blind and disabled, Medicare work performed by SSA and certain other work. For reasons of economy and efficiency, SSA has integrated administration of both trust fund and some nontrust fund programs. The Social Security Act authorizes payment of SSI and certain other nontrust fund administrative expenses from this account, with full reimbursement from general funds in other accounts.

Of the new FY 1990 budget authority requested:

- o $1,118 million is for administering the old-age and survivors insurance program,
- o $1,257 million is for the disability insurance program,
- o $1,111 million is for administering the SSI program,
- o $180.1 million is for SSA's Medicare support functions,
- o $86.3 million is for processing annual reports of earnings,
- o $32.8 million is for annual SSA purchase contract payments on buildings previously constructed under the purchase contract method of financing, and
- o $47.9 million is for a contingency reserve.

Included in the first five activities is $203 million in budget authority for automated data processing and telecommunications activities and $750 million for the Disability State Agencies.

Automated Data Processing (ADP) and Telecommunications

SSA expects to obligate about $178 million in FY 1989 and $203 million in FY 1990 for the lease and purchase of ADP and telecommunications hardware and software, supplies, and contractual services. Beginning with FY 1989, these computer and telephone-related expenses are funded on an annual basis like the rest of the LAE account, with no carryover of unobligated balances into future years.

In FY 1989, SSA's plans for continued systems modernization are limited by the cap of $167,960,000 in the FY 1989 appropriations act. This new budget authority, plus funds carried over from FY 1988 and potential recoveries of prior year obligations result in estimated obligations of $177.7 million in FY 1989. Basic, ongoing computer and telephone-related operations require over $150 million annually, leaving little left over for continuing systems enhancements. With the cap in the FY 1989 appropriation language, SSA is prohibited from using additional funds for automation projects. For these reasons, and to achieve savings required to absorb the January 1989 Federal

pay raise, SSA has submitted a FY 1989 supplemental requesting that the cap be deleted from the appropriation language. This would permit SSA to allocate more resources to ADP and telecommunications activities within the amount of the total LAE appropriation.

For FY 1990, SSA requests $203 million for ADP and telecommunications funding, without a restrictive cap which reduces the Agency's flexibility to manage resources efficiently. In addition to ongoing operations and maintenance, this budget will fund projects in the following categories:

- o Systems analysis and software services, including contracts to develop and improve programmatic and administrative software, and continuation of services of an integration and management contractor for overall management of SSA's systems improvement.
- o Telephone service, to provide modern telephone equipment and services, including expansion of toll-free "800" number service nationwide.
- o Hardware and equipment upgrades, to provide needed additional computer capacity for the increasing number of online transactions and for implementation of other software improvements resulting from SSA's efforts to modernize.
- o Office automation, to increase productivity and to improve the quality of work and work environment of SSA employees.

Disability State Agencies

The budget request includes $750 million for the Disability State Agencies in FY 1990. This represents a net increase of $2 million, or .3 percent, over the FY 1989 operating budget of $748 million. State agency workloads decrease by 67,000 cases or 2.6 percent. Nationwide, State agencies have made significant productivity improvements, while maintaining high quality disability determinations. From a national average of about 194 cases per workyear in FY 1987, productivity improved to 210 cases per workyear in FY 1988. We are budgeting for continued improvement in FY 1989 and FY 1990, with the national average production rate targeted at 217 cases per workyear in FY 1990. This additional improvement in productivity will result from work

simplification efforts, as well as from the correction of staffing imbalances and achievement of more uniform productivity among the States.

Federal Staffing

SSA has budgeted for Federal employment levels consistent with efficient processing of its workloads as well as completion in FY 1990 of its 6-year full-time equivalent (FTE) reduction plan. We have projected workyear requirements based on the volume of work SSA expects to process in fiscal years 1989 and 1990. Our budget request takes into account the productivity actually achieved by SSA's workforce during FY 1988 as well as the management, procedural and automation improvements which will affect the time it will take to process work in FY 1989 and FY 1990.

For this account, SSA is requesting 63,911 workyears for FY 1990, a decrease of 1,948 workyears from the FY 1989 level of 65,859 workyears. To achieve its overall workyear needs, SSA relies on a mix of FTEs, noncelling employment and overtime workyears. In FY 1990, we plan to use 63,007 FTEs, 460 workyears of noncelling employment (principally summer youth employment), and 444 workyears of overtime. The most significant item of administrative savings reflected in this budget is the phased implementation of the Modernized Claims System for Social Security claims. Through FY 1988 this initiative has already saved nearly 1,000 workyears, and additional savings of more than 2,000 workyears are projected for the 2-year period, FY 1989 and FY 1990.

Other factors which will contribute to reduced workyear needs in FY 1990 are:

- Office automation and streamlining of field office work measurement systems.
- Direct entry and edit correction capability for processing center benefit authorizers through an online interactive system able to identify inconsistencies in information as it is input into the Master Beneficiary Record.

These and other changes will help us to realize our goals to process budgeted workloads, maintain our level of service to the public and continue initiatives towards a more streamlined, efficient organization.

BIOGRAPHY OF DORCAS R. HARDY

Dorcas R. Hardy was sworn in as the 10th commissioner of Social Security on June 26, 1986, by HHS Secretary Otis R. Bowen, M.D. She was nominated by President Reagan on March 20, 1986, and confirmed by the Senate on June 19, 1986.

As commissioner of Social Security, she is the chief administrator of the nation's Social Security programs — Old Age and Survivors Insurance and Disability Insurance — as well as the Supplemental Security Income program for the needy aged, blind and disabled. These programs combined provide monthly income to over 39 million people at an annual cost of $223 billion.

Ms. Hardy also serves as chairman of President Reagan's Task Force on Legal Equity for Women.

Before becoming the commissioner of Social Security, Ms. Hardy had been HHS assistant secretary for human development services since May 8, 1981. As assistant secretary, she was responsible for administering human services programs of $6 billion for children, youth and families; the elderly, the disabled and Native Americans; and funding to states for social services to help low-income families.

She was born in Newark, N.J., July 18, 1946, and grew up in the Oranges, N.J. Ms. Hardy received her B.A. degree in 1968 from Connecticut College and an M.B.A. from Pepperdine University in 1976. She also completed the Executive Program in Health Policy and Financial Management at Harvard Business School.

Prior to federal service, Ms. Hardy was associate director of the University of Southern California's School of Medicine Center for Health Services Research where she established a multi-disciplinary health and social policy research organization.

From January 1973 to April 1974, Ms. Hardy served as California's assistant secretary for health under then Governor Ronald Reagan. She was executive director of the Health Services Industry Committee of the Cost of Living Council from 1971 to 1973. From April 1970 until June 1971 she was special assistant to the national chairman and director of the White House Conference on Children and Youth. Earlier, she worked as an aide to Senator Clifford P. Case of New Jersey.

Ms. Hardy has authored and co-authored a number of published articles, several of them relating to the automation of hospital information systems and the rights of children.

Ms. Hardy has been the recipient of numerous awards for her outstanding public service including the highest achievement award given by the Council of Jewish Federations and The Tomas Rivera Award given by the National Hispanic University. In addition, she has been recognized by One Church, One Child, the National Committee for Adoption, the North American Council on Adoptable Children, Inc., the National Association of Area Agencies on Aging and the National Humanitarian Award from the Coalition of Hispanic Mental Health and Human Services Organization.

In California, she was vice president of the Junior League of Pasadena, on the board of directors of the Sierra Madre Girl Scouts Council, and All Saints Children's Center. In 1968, she was chosen by the Girl Scouts of U.S.A. to represent the organization in Pakistan. She was cited for her achievements by Who's Who of American Women, 1978 to the present, and Outstanding Young Women of America, 1978 through 1983. In 1985 she became a member of Phi Beta Kappa.

SUMMARY OF REQUEST

Ms. HARDY. Thank you, Mr. Chairman. I am here to present the Social Security administrative budget. I have a brief handout for your staff, and I would like to review that with you. It shows some of the things you have already noted.

We are large. We are paying 40 million beneficiaries $20 billion in program benefits every month. Our administrative budget is $3.833 billion which comprises mostly payroll and expenses, disability determination services, a small contingency reserve and resources for information technology systems, of which 80 percent is maintenance, ongoing work, and computer tapes.

Our workloads are growing. We process 6 million new claims a year, and by the year 2000, our postentitlement actions, like changes of address and adjustments of benefits based on earnings, will go from 72 million to 79 million annual transactions. We are still issuing about 13 million Social Security cards a year, either new or duplicate. That took us 6 weeks to do in 1982. Today it takes us 5 to 7 days.

We process more than 254 million annual wage reports, which in 1982 took us 48 months to complete. In 1988 it took us 5 months. In terms of monthly benefits, we expect that we will rise to about 47 million beneficiaries in the year 2000. And, since there has been a lot of discussion about telephones lately, I thought I would let you know that we process about 50 to 60 million phone calls each year.

We do need our systems, our technology, to provide that kind of support, not only for the American public, but for our excellent staff. We also should comment that paper is still with us. I was doing an analysis of file folders and we can count more than 100 million file folders in Social Security, which would go about two-thirds of the way around the world.

So at some point our systems have to address the problems with paper and the problem of what to do about that in the future.

We have new services that did not exist in 1982. We have a new claims system which includes 25,000 terminals in our 1,300 offices. We have automatic enumeration at birth upon request so parents can apply for a Social Security number at the hospital.

We have a new personal earnings and benefits estimate statement for the American worker, not the beneficiary, but the workers, the people paying those taxes, which shows an estimate of what Social Security benefits they will get in the future. We have more than 9 million people who have been interested in that.

We also have the option of contacting Social Security through our 800 number that will be nationwide by next fall. We have had 22 million calls so far.

The next-to-the-last chart here shows that this has not been an easy time, as you have pointed out. We have downsized since 1984 by approximately 21 percent. We have almost completed the downsizing. That is 17,000 fewer employees in the Social Security Administration than in 1984. Had we not downsized, we would be requesting $600 million more in this year's budget, and over the last 5 years, we would have requested $2 billion more in administrative expenses.

We think we have been able to provide—and our surveys bear this out—good quality public service in spite of the downsizing and the uneasy times that we have been going through.

We have also increased our productivity and we feel very proud of providing good service to the American public.

So, in summary, we have good quality public service and the dedicated well trained good staff to do the job. In addition, we need good technological support in order to provide those services. For all that, we request $3.833 billion.

Thank you, Mr. Chairman.

Senator BUMPERS. Go ahead, Mr. Chairman.

Senator HARKIN [presiding]. Go ahead, Senator Bumpers.

Senator BUMPERS. No.

STAFFING LEVELS

Senator HARKIN. Let us talk a little more about the staff cuts; 1990 is the last year of a long-term plan to reduce staff by 17,000. You have already cut 13,000 below the 1984 levels and by 1990 you plan to have only 63,000 staff, a cumulative reduction of 21 percent.

Again, you believe that you can do this without hurting the quality of the services to the public?

Ms. HARDY. Yes; we do, sir. We also believe that beyond 1990 we should have a level 63,000, and that is what we have requested in 1990.

Senator HARKIN. Will you oppose any further staff cuts after 1990?

Ms. HARDY. I would.

TOLL-FREE TELEPHONE SERVICE

Senator HARKIN. How many additional staff do you need to improve the quality of the 800 telephone service? I am getting complaints about the service. Obviously it is being well used.

Ms. HARDY. Yes, sir.

Senator HARKIN. How many staff do you have now operating it?

Ms. HARDY. We have about 2,000 operating the teleservice centers throughout the country. Some 50 percent of our country has been handled by teleservice centers since the early 1970's, and it takes about 2,000 people to operate these centers. We will be adding about 500 to 800 new staff from outside the agency this year to do the phones.

Senator HARKIN. 500 more staff for the 800 service?

Ms. HARDY. Yes, sir; that will bring us up to approximately 3,000 by October 1, of both supervisory as well as teleservice representatives, whose primary function will be phone service.

DISTRICT OFFICES

Senator HARKIN. Even though you have had a 21-percent drop in staff, you still have 1,300 district offices?

Ms. HARDY. Yes, sir.

Senator HARKIN. Are you still pledged to maintain those 1,300 district offices?

Ms. HARDY. I expect that we will; 10 years from now, we will have approximately the same number of offices. We made the commitment to have face-to-face contact as an option for the American public. I see the offices getting smaller and I see them getting more generous in terms of some of our staffing, which will be positive.

We have to work a lot of staffing out. I see approximately the same number of offices. We vacillate, we open some, we move some. We have had basically 1,300 for quite a few years. It is approximately that.

BUSY RATES FOR TOLL-FREE TELEPHONE SERVICE

Senator HARKIN. We have covered the phone system. I see a 30-percent busy signal rate.

Ms. HARDY. There has been some discussion, Mr. Chairman, about busy rates as I testified earlier this week. Maybe I could try to set the record straight.

As I said, what we are aiming for is one number that the general public can use to reach the Social Security Administration. They still would have that entry point, so to speak. Then they would have their claim taken through an appointment at a local office, still have the face-to-face option, or they can have their claim taken on the phone.

We started out in October. We had 30 percent busy signals over the last couple of years with all of our 700 different phone numbers. My commitment to you is to reach a 5-percent busy signal where no more than 50 percent of the callers would be put on a line in a queue and would have to wait more than 1 minute.

I expect we will be able to get to that point by next fall by the expansion of the phone service. Yes; we had trouble in January. We had 800,000 calls in 1 day. We can't possibly answer all of those calls on the first ring, and it would be poor management to staff accordingly.

Senator HARKIN. Is that mostly inquiries about catastrophic insurance?

Ms. HARDY. There are a lot of catastrophic questions, tax time questions; here it is a new year, what do we do with earnings, the earnings test goes up, what about the earnings test? They call for a lot of information. In January, we had 800,000 calls in 1 day, and we did have over 30 percent average busy signal rates for the months of January and February.

ACCURACY OF TELEPHONE ANSWERS

Senator HARKIN. In January, an internal Social Security Administration study showed an alarmingly high percentage of wrong answers were given out. For example, wrong answers were given in 24 percent of the calls involving supplemental income.

Ms. HARDY. First of all, the busy signals were higher in January and February. We are now down to about 9.3 percent in March, and we expect to maintain that until next year and then go down further. On the accuracy rates, the new surveys that we did in March show that we are above 95 percent on accuracy.

The Supplemental Security Income Program is extremely complex, as are all of Social Security's programs, that vary State by

State. We did some new training with everybody and we think that the accuracy is much higher.

Senator HARKIN. Are you tracking it?

Ms. HARDY. Yes; we are. We are monitoring our phone people and we are going back and asking them very technical questions. We also track what the callers ask.

DISABILITY HEARINGS AND APPEALS

Senator HARKIN. I do not know if you were here for my opening statement before HCFA this morning, but I said that in Iowa, it routinely takes 6 months for a disability claimant to get a hearing date scheduled. That is a half year of people surviving while waiting to hear from your agency. Usually these people have already been unemployed for several months, have probably got a family, are trying to make ends meet, and they have to wait 6 months to even get a hearing scheduled.

How can these people be expected to support themselves and their families while waiting 6 months and what can you do to shorten these delays?

Ms. HARDY. We are equally concerned about delay. The whole process averages 700 days.

Senator HARKIN. 700 days is average?

Ms. HARDY. That is why I have asked for a total review of the appeals process.

Senator HARKIN. Wait a minute.

Ms. HARDY. From the beginning. You start with Social Security and say, hello, I would like to have disability insurance, all of the way to the final disposition, including all of the appeals. In other words, if you are denied and then you are reconsidered and then denied and then reconsidered again, it could take 700, 696 days.

I have asked Mr. Enoff to be here. Basically there are a lot of things that go into this When someone comes into the Des Moines office and says, here I am to appeal, we have to go back, talk to the lawyers, get new medical evidence. It is a very lengthy process and we are trying to figure out how better to speed this up.

Mr. ENOFF. The Commissioner asked us to do a complete review of the hearings and appeals process because of the delays in the process that are built in.

You mentioned Iowa. Unfortunately also in the rest of the country, it can take up to 6 months to schedule those hearings because of the process there.

We had an unfortunate situation where the first draft of new regulations were publicized recently before they were ready for review. As a result of that, the Commissioner asked us to take a three-pronged approach in reviewing the appeals process. That is well along the way.

We appointed the Disability Advisory Council members to a committee. They held public hearings in Los Angeles as well as in Washington last month. They will be meeting again next month and providing us with some recommendations based on their public input by June.

We also contracted with the Administrative Conference of the United States to do a thorough study of the administrative appeals process and make recommendations to us by this summer.

Third, we asked a panel of experts to come in and consult with us, former Commissioners, former Secretaries, former General Counsels, who have experience in this area. I met with that group one time and gave them a briefing.

Once we have these two other reports, we intend to meet with them again in July or August and get individual recommendations.

So we would like to make some reforms in that process. Essentially it hasn't been reviewed since 1940 when it was set in place, when there were no representatives involved in the hearings.

The process has changed somewhat. We are aware of that; 80 percent of the claimants who come to a hearing now have someone, usually a lawyer representing them. We want to make some changes to take that into account and yet we want to preserve the rights of the individual to take the steps necessary.

HEARINGS REVERSAL RATES

Senator HARKIN. You know what else I would like to see? I would like to see the reversal rate, of the district court and the circuit courts, on these appeals.

Mr. ENOFF. I don't have that. I would say the reversal rate has been coming down to the level it was prior to 1982–83, in the last 3 or 4 years since we had the reform in 1984. There has been a high remand rate in the last few years because of some of the provisions in the 1984 amendments.

The medical improvement process, the new mental regulations, have caused a very high number of remands, but the reversal rate at the court level has been coming down to the level that it was prior to 1982.

Senator HARKIN. What is the difference between remand and reversal?

Mr. ENOFF. Well, sir, the court may remand a case to the agency and say, take another look at this case because I think there has been some change or something you overlooked. The courts do not like to reverse the cases. I would say that the majority of cases that are remanded are reversed, that is, allowed.

Senator HARKIN. Would you provide to this committee the data on reversal rates and also for the different circuits remands? I would like to see this data. My perception is that the reversal rates are quite high.

[The information follows:]

PERCENTAGE OF ALLOWANCE DECISIONS

The following charts show that the percentage of allowance decisions at the court level has declined in recent years; however, there has been a high level of remands and the majority of remanded cases are allowed

The first chart shows all court decisions in fiscal year 1988 displayed by circuit. Only 30 percent of these decisions were reversals, that is, decisions in which the claim was allowed.

The second chart shows decisions made in fiscal year 1988 for cases remanded to SSA from the courts. As stated during the hearing, remands are more likely to result in reversals; 74 percent of these decisions were reversals.

The third chart shows the trends in percentage of court decisions and remand decisions that were allowances in recent years. These figures are not available in a circuit-by-circuit breakout.

SOCIAL SECURITY ADMINISTRATION LITIGATION STATISTICS

FY 1988

COURT DECISIONS BY FEDERAL CIRCUIT

CIRCUIT	1	2	3	4	5	6	7	8	9	10	11	DC	TOTAL
Total Decisions	467	430	462	834	505	2257	314	596	850	121	724	30	7590*
Affirmations	302	136	276	477	349	1567	217	325	543	60	428	18	4698
Reversals	64	247	153	305	97	604	70	216	201	52	238	8	2255
Dismissals	101	47	33	52	59	86	27	55	106	9	58	4	637
Decision Rates	100%												
% Affirmations	65%	32%	60%	57%	69%	69%	69%	55%	64%	50%	59%	60%	62%
% Reversals	14%	57%	33%	37%	19%	27%	22%	36%	24%	43%	33%	27%	30%
% Dismissals	21%	11%	7%	6%	12%	4%	9%	9%	12%	7%	8%	13%	8%

*There were also two Supreme Court decisions, making a total of 7592 final court orders in FY 1988.

FULLY FAVORABLE DECISIONS ISSUED ON COURT REMANDS
(AC DECISIONS ON ALJ RECOMMENDED DECISIONS) 1/
FY 1988

	FAVORABLE DECISIONS	TOTAL DECISIONS	% FAVORABLE
1st Circuit	166*	286*	58%
2nd Circuit	290*	498*	58%
3rd Circuit	321	553	58%
4th Circuit	369	606	61%
5th Circuit	195	336	58%
6th Circuit	364	722	50%
7th Circuit	143	246	58%
8th Circuit	360*	552*	65%
9th Circuit	315	530	59%
10th Circuit	53	90	59%
11th Circuit	360	618	58%
D.C. Circuit	2	14	14%

*Includes the exact number of decisions for 11 months and an average for one month to reflect the complete fiscal year.

1/This chart does not include about 800 cases in which the Appeals Council (AC) allowed benefits without remanding the cases to an ALJ. The data for those 800 cases cannot be broken out by circuit. Of all remands processed by OHA in FY 1988, 74 percent were allowed.

SSA LITIGATION SUMMARY: FY 1984 THROUGH FY 1988

	FY 1984		FY 1985		FY 1986		FY 1987		FY 1988	
	No.	%	No.	%	No.	%	No.	%	No.	%
Court Decisions										
Affirmations	2785	36%	4261	40%	4399	49%	4084	60%	4700	62%
Dismissals	520	7%	1419	14%	1141	13%	505	7%	637	8%
Reversals	4361	57%	4888	46%	3420	38%	2242	33%	2255	30%
Total	7666		10568		8960		6831		7592	
Court Remands Processed										
Affirmations	1896	33%	2389	22%	2112	24%	2855	28%	1127	19%
Reversals	3066	53%	4905	45%	6118	68%	6984	68%	4317	74%
Other	818	14%	3569 1/	33%	749	8%	478	4%	396	7%
Total	5780		10863		8979		10317		5840	
Medical Cessation Remands 2/			8181		164					

1/ Includes a large number of cases pending in OHA when the 1984 Amendments were enacted that required special disposition to comply with the provisions of the law.

2/ Remands resulting from the 1984 Amendments.

Mr. ENOFF. As I say, they are coming down. Let me point out, too, if I might, Mr. Chairman. In this process, and I am not taking away from the problems in the appeals process, but of the people on the disability rolls, 78 percent come on the rolls at the initial application of the disability determination service.

And that is done within 75 days of application. So while the rate is high, only about 15 percent of the applicants ever get to the administrative law judge stage.

Senator BUMPERS. What percent?

Mr. ENOFF. About 15 percent get there. Of that, a little over one-half are allowed. So out of 100 people who would apply for disability, 36 would come on based on the first application. Of the 64 who are denied that first application, only 30 appeal.

Of those 30 who appeal, the first appeal is at the reconsideration stage. At the reconsideration level, of those 30, 4 are allowed or reversed and 26 are denied again. Of those 26, 15 go to a hearing. And of those 15, 8 are allowed and 7 are denied. Out of those seven denials, less than one goes to court.

I would be glad to supply, I don't have one here, a little chart that is used in this process.

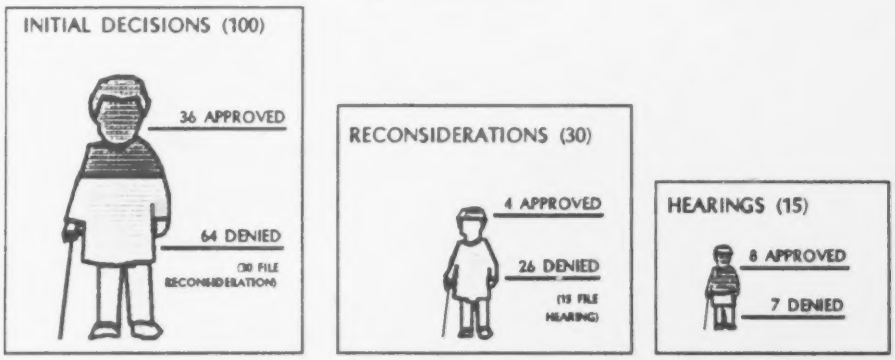
Senator BUMPERS. We are really interested in statistics. Is that the statistic?

Mr. ENOFF. That is. I am not sure of the total at this point but we would be glad to provide you with a copy of that.

Levels of Disability Allowance Determinations

FY 1987

(per 100 cases)



Senator BUMPERS. I wish you would.

Mr. ENOFF. I think that is something that we have to keep in mind in the process as we go about reforming, not that we don't want to change the appeals process, but that we are talking about the person who is waiting, unemployed. And of those people who come on, who are finally eligible for disability, about 70 percent come on in the first 2½-month period.

Ms. HARDY. This is not to say that we are not concerned about those others, but it is a much smaller group than is usually assumed.

DISABILITY DENIALS

Senator HARKIN. There is a perception that many times hearing scheduling is held up for long periods of time hoping the applicant will just go away and they won't appeal. People also have the idea that there is some built-in factor in the administration of the program, that says, we will deny 15 percent of the requests.

Remember what happened back in the early 1980's? Can you assure me that that is not taking place?

Ms. HARDY. No, sir.

Mr. ENOFF. Absolutely not.

Senator HARKIN. In Iowa, it is actually 264 days. That is 9 months.

Mr. ENOFF. I believe, Mr. Chairman, that was the statistic from the time of filing to the time of final disposition.

Senator HARKIN. Here is New York—179 days.

Mr. ENOFF. Let me say that in Iowa, the Des Moines office, has been one of our best offices. We had a little problem there last winter. In March, the chief judge was out there. We had two new judges in that office and several new clericals.

I am happy to tell you that the March statistics are better than February. We believe that it is going to continue to improve. One thing that has happened there, though, is there is an increase in the requests for hearings in Iowa. It jumped up. We continue to track that. And if that continues we will, of course, have to add additional judges.

Senator HARKIN. Senator Bumpers.

VERIFICATION OF SOCIAL SECURITY NUMBERS

Senator BUMPERS. Ms. Hardy, you have seen this morning's New York Times, haven't you?

Ms. HARDY. I have heard about it. I have not read it.

Senator BUMPERS. Is it fair to assume that we are not going to have any more of this TRW credit information sharing?

Ms. HARDY. What I assume it says is that I stopped giving that.

Senator BUMPERS. No; it does not say that you did stop it. It says that the office stopped. Have you?

Ms. HARDY. I have stopped it as of now. Basically I got together with our Policy Council and our attorneys and said let's look at the whole big issue. I think everybody is concerned about it, but we have several conflicting things. I was talking to some of our authorizing chairmen on both sides of the Congress yesterday and we may need some legislation that will help us out on this.

You have the Privacy Act. We have the Freedom of Information Act. We have people who are signing freedom of information forms in order to verify Social Security numbers.

On the other hand, we want to protect confidentiality and we want to protect the record.

Senator BUMPERS. It says what you were doing with TRW is clearly illegal.

Ms. HARDY. I dare say if you put two attorneys in the room on this issue you will have two opinions. I have not read that yet either. I have asked the policy council to present me with a decision by the end of the month about where we should go on this issue.

Senator BUMPERS. Who is Mr. Gonya?

Ms. HARDY. Don Gonya is the chief counsel for Social Security in the Office of the General Counsel at HHS.

Senator BUMPERS. He says while the tape prepared by the Social Security Administration for the requester, TRW, would say nothing explicitly about the other Social Security number named combinations on the tapes submitted by the requester, the obvious implication will be that the Social Security Administration's records show that such Social Security numbers are associated on the tape furnished by the requester.

Ms. HARDY. We negatively verify. In other words, we would say, if somebody said, "Is Hardy's number 222-22," we would say no. We would never say what Hardy's number is. That would be a release of private data. Freedom of information is involved here in terms of negative information.

So we are caught in the middle, I think.

Senator BUMPERS. I do not believe you are, Ms. Hardy.

Ms. HARDY. The attorneys have other opinions that say that negative verification is perfectly in order to protect the integrity of our records and to make sure that someone's earnings are posted correctly.

Senator BUMPERS. That is not what they are asking for. They are asking for credit information. This is the biggest credit organization in America and they want to update their records and they want to be sure that they are getting the right numbers and they are asking you to validate that.

Under the Freedom of Information Act, I can call the FBI and say send me everything you have got on me, or I can call the Social Security Administration and get anything you have on me, but I don't want Tom Harkin doing that, asking about me. I don't even want him to know my Social Security number.

Ms. HARDY. But if there is a form that you filled out that you sent to someone, and we had this come up before, and they send it with your signature, should we honor that?

Senator BUMPERS. Why would you?

Ms. HARDY. Those are the kinds of questions we face.

Senator BUMPERS. You are not in the moneymaking business. I understand you will charge $10 per thousand names. That is the fee arrangement. Is that correct?

Ms. HARDY. There are some discussions that this would cost $1 million and they would pay $1 million.

Senator BUMPERS. Social Security, No. 1, is not in the business of performing services for the private sector for money.

When I was Governor I stopped the revenue department from giving out driver's license information because you start getting Saturday Evening Post if you happen to be on the list or you get a request to subscribe to the Saturday Evening Post when you start sharing that information. And though the revenue department is convincing you they were making $1 million or $2 billion a year

out of furnishing this information to all of these organizations that do mail solicitations, I just stopped it. I think, frankly, they are doing it again now. I just do not think the Social Security Administration has the right to say to somebody, yes, that is Dale Bumpers' correct Social Security number.

Ms. HARDY. We would never say that.

Senator BUMPERS. What would you do?

Ms. HARDY. We would only say that *x* number is not your number.

Senator BUMPERS. You are getting into a little sophistry there.

Ms. HARDY. No; attorneys have lots of opinions on this thing.

Senator BUMPERS. I will do my best to resolve this for your attorneys and you and everybody else.

Ms. HARDY. That is fine. And I expect everybody is concerned about it and that is why I put a stop to it. We are concerned about protecting the integrity and confidentiality and the privacy of the numbers. Everyone uses the number, but we all believe that it is private. I am going with the privacy discussion here and hoping that we can come up with the best way to solve it.

Senator HARKIN. Can I interrupt you a second on this? I just want to make sure I enter into the record at this point a letter from Senator David Pryor, your colleague from Arkansas, who is chairman of the Special Committee on Aging about this very subject.

[The letter follows:]

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC, April 11, 1989.

Hon. TOM HARKIN,
Chairman, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies, Washington, DC.

DEAR TOM: Knowing of your intention to hold a hearing tomorrow on fiscal year 1990 appropriations for the Social Security Administration [SSA], I would like to bring to your attention two issues that were the focus of a Special Committee on Aging hearing I held yesterday morning which merit your immediate attention.

First, SSA has encountered serious problems in implementing its nationwide toll free telephone service program. Secondly, the Social Security numbers of millions of Americans have been verified on Social Security computer files with the names of individuals on magnetic tapes supplied by private companies such as credit agencies and banks. At a time when the SSA has requested an increased appropriation for expanding its computer and telecommunications systems of $33 million in fiscal year 1990, I urge you to review these requests with caution until you are satisfied that SSA is committed to addressing the problems raised at yesterday's hearing.

As you know, SSA's current timetable calls for full implementation of the new toll-free telephone system by October 1, 1989. One of the primary issues examined at the hearing was whether the performance of this new system justifies its extraordinarily rapid implementation.

The testimony of the Director of the Income Security Issues for the General Accounting Office [GAO] outlined a number of problems that raise serious doubts about the advisability of fully implementing the 800 number system according to SSA's schedule. In fact, GAO recommends that further expansion of the system be carefully phased-in, contingent upon the agency sustaining a reduced busy signal rate. I believe that this and other GAO recommendations represent a sound and prudent course for SSA to take with respect to further implementation of SSA's 800-number service. In view of your hearing tomorrow, I am enclosing a copy of GAO's testimony for your review.

In recent weeks, I have learned about another extremely serious problem about SSA's management of the program. Much to my dismay, I have discovered that SSA has verified millions of Americans' Social Security numbers for private companies

such as credit bureaus and banks. I believe this is potentially the largest breach of confidentiality in the history of the program.

For example, SSA performed a test run 151,953 names for TRW which were completed in 1978. SSA was then preparing to run 140 million names for TRW. They asked TRW for $1 million for the information processing, and TRW agreed. How, I would ask, can SSA honestly argue before Congress that they lack adequate computer resources to accomplish program purposes if they expect to find the spare time to run a million dollar job for TRW? SSA has already run 3 million names for Citibank, and I am investigating how many other abuses have occurred. Over the last several days, my staff has provided documentation to your staff about this grave matter and I hope you find this information to be useful.

These disclosures to private companies are, in my opinion and in the opinion of the American Law Division of the Congressional Research Service, in violation of the Privacy Act of 1974. During tomorrow's hearing, you might want to ask for a full accounting of how much computer time was used in processing each nonemployer private sector request.

If you would like any further documentation related to these important issues, please do not hesitate to contact my Aging Committee staff. I look forward to working with you to assure that we are improving, and not reducing, access to and quality of services provided by the Social Security Administration.

Sincerely,

DAVID PRYOR,
Chairman.

TEST RUN FOR TRW

Senator HARKIN. You performed a test run of 151,953 names for TRW. What I would like to know is, when they came to you and wanted to test run these, who approved that, who signed off on that?

Ms. HARDY. I do not know. I would have to find out.

Senator HARKIN. Would you find out and please tell us? I want to know the individual that approved that test run.

Ms. HARDY. Glad to. Could I just also comment that the Senator has quoted Mr. Gonya's memo saying that we can't do that. In the same memo he said we find nothing in the case law which directs a finding here constituting clearly unwarranted invasion.

There are two sides of this from the attorneys. I stopped it because everybody has two sides to the issue. We need to come up with a better policy to make sure that we don't reveal anything.

[The information follows:]

NEGATIVE VERIFICATION FOR TRW, INC.

Based on our interpretation of the Freedom of Information Act at the time of the TRW request, it appeared the agency was required to provide negative verification. For that reason the request was approved routinely by staff without my knowledge or approval.

Senator HARKIN. Again, I want to know who OK'd that. I want to know if it has ever been done before.

Ms. HARDY. It is my understanding it has been done before, yes.

Senator HARKIN. Names were sold?

Ms. HARDY. They weren't sold, sir. We are just recovering our costs of running a tape. If it costs $1, we say, please give us $1.

Senator BUMPERS. We have got enough problems with our ITS system over there without taking on TRW and everybody else. If we do this for them, you are going to be opening up a flood tide. If you are only going to be doing it to recover your costs, why do it?

Senator HARKIN. Let me ask a further question. Go ahead. I am sorry.

Ms. HARDY. Because some of the attorneys will argue with you that, under some of the statutes that we currently have, we should be doing this because of the Freedom of Information Act.

Senator BUMPERS. Freedom of information is directed to the person who wants the information about himself. TRW has no freedom of information regarding me.

Ms. HARDY. An individual has signed.

Mr. ENOFF. The Commissioner has asked that the policy be looked at in terms of what has been done and what should be done. In the past, in addition to employers, there are others who have requested verification of numbers.

Never, to my knowledge, did we ever supply an actual number. But they have come in for verification and sometimes these are organizations that have a statement from the individual that says, I authorize this company to have the information from my account.

When the TRW request came in, we found that staff, that routinely verify information for employers and these others, had done some verification for other companies. I do not know if we will find out who specifically authorized this action, but I think what happened is they followed the procedure for employers thinking that that was the same process which should be used.

Senator BUMPERS. Here is what the Privacy Act says: No agency shall disclose any record which is contained in a system of records by any means of communication to any person except pursuant to a written request by or with the prior written consent of the individual to whom the record pertains, unless disclosure of the record would be covered by any of the exemptions. Now, 12 exemptions.

Now, that is my point. You would never suggest that 151,000 people had sent you——

Ms. HARDY. Prior written consent?

Senator BUMPERS. Yes; prior written consent.

Ms. HARDY. They have signed a form, it is my understanding.

Senator BUMPERS. That all 151,000 people at TRW asked you to validate the number on?

Ms. HARDY. No; when you sign a form, it is just like when you apply for a mortgage. You sign saying that all of the information on the form can be verified by this company.

Senator BUMPERS. Did TRW send that on each one of those names? They sent you a list of all 151,000 people and the consent form that each one of them had signed saying you may release all of this information?

Ms. HARDY. A way to look at it is that if they have all of that in their file, that could be gone back to.

Senator BUMPERS. Commissioner Hardy, if you want to, if I send you a notice and say you can furnish anybody you want to any information on my file, that is one thing, but if I apply for credit with somebody, and they call TRW and say is this guy worth anything or is his credit good, and they say I do not know, we will call Social Security, first of all, and validate his Social Security number and make sure he is not lying about that, I am just as innocent as a newly ordained nun. I do not know all of this is going on.

It is not the biggest thing in my life, but the FBI checking the libraries is offensive to me. TRW asking the Social Security Administration to validate numbers is offensive to me. I just have a very

strong feeling about people getting information from public institutions.

I don't want the IRS doing it, and I am not sure that they are not involved in some way in this same kind of activities, different, but the same offense, as far as I am concerned.

So I am going to do my very best the first opportunity coming through here to put this to bed for you and you won't have to worry about it.

Ms. HARDY. That is why I stopped it, sir.

ARMSTRONG AMENDMENT VOTE

Senator COCHRAN. There is a vote on the floor right now that you did not know about.

Senator BUMPERS. Are you serious?

Senator COCHRAN. You have got plenty of time to make the vote. I was just telling the chairman that there is a vote in progress on the floor, the Armstrong amendment, earned income tax credit.

You have about 3 more minutes. It is all right for you guys to stay here. You will probably vote wrong anyway.

Senator BUMPERS. Let me ask you about that and put a hold on it, Ms. Hardy.

Ms. HARDY. It is my understanding the first year is revenue neutral; that there is no cost.

Senator BUMPERS. Are we phasing out every year that we raise the current income? So 4 percent on top of that is a lot of money, is it not, or in the out years, in the out years?

Ms. HARDY. We raise it anyway.

ADEQUACY OF THE AGENCY'S REQUEST

Senator COCHRAN. In the absence of the chairman I was asked to go ahead and proceed with any questions that I might have. I am more interested in the issue before us which is really the budget of the Social Security Administration for the next fiscal year.

I think that is why we are having a hearing and we are interested in knowing what the budget request is in terms of funding for the activities of the administration of the Social Security Act, Social Security programs.

Could you give us your reaction to this in terms of the adequacy of the request? Have there been any developments or do you foresee any that the committee ought to be aware of in terms of assessing the adequacy of the requested funding for the agency?

Ms. HARDY. I think there are a few things, Senator. The agency has downsized considerably. This is the last year of our downsizing. As the chart that you have points out, in the small circle, most of our dollars are for payroll and expenses. So we have been able to achieve our downsizing because we have had some very good productivity increases over the last couple of years, partly through computerization but partly through better management.

So we see an increase in our request from our operating budget this year in the payroll costs. It does not include a pay raise, but it does include some additional dollars that we believe we need in terms of health insurance and other kinds of coverage for payroll and expenses.

It also includes increased costs for rental and dealings with GSA, et cetera.

The State part of the chart represents the disability determination services [DDS] in each of the States, I would like to comment that the Mississippi DDS is one of the best DDS's in the entire country. We are very pleased with them and most appreciative of their good work.

Senator COCHRAN. DDS, I can't remember all of these acronyms.

Ms. HARDY. Disability Determination Service. They make that initial assessment as to whether or not you are disabled. We expect to pay all of the States about $750 million in fiscal year 1990. We have been working very carefully and closely with all of the States in order to get the program better managed over the last couple of years. They have not had any significant increases and they have been squeezed and still have done a good job. We are real pleased with them, at least in Mississippi.

The other large chunk of our budget, though it is a small percentage, is for our information technology systems. Information technology systems is all of our computer systems and software that we need so that we can provide better support to our staff.

We think we have made significant strides in that area. But there have been a lot of questions as to whether or not the systems are running well and whether it has been a positive kind of thing.

I think we have done a good job. Most of our dollars are for just keeping the system running so we can support our staff in the field. We are now taking 6 million new claims a year and we think that that is a lot of work out there.

We also asked the National Research Council of the National Academy of Sciences to give us an assessment of our systems and to tell us how well we are doing. They have written to me recently saying they believe that we are doing quite well. There is the need for further improvement especially in the area of making sure that we have a backup. So if we have a severe fire or anything else in our national computer center, we will have some other place where we can make sure our computers keep running.

So we think we have been quite cost-effective and we think our budget is very tight in 1990.

SUPPLEMENTAL APPROPRIATION FOR 1989

Senator COCHRAN. There is talk about a supplemental appropriations bill this year coming over to the Senate from the House. As I understand it, there has been a request from your agency to increase computer spending over the $170 million ceiling established in this year's appropriations bill.

Is this something that you are formally requesting the committee include in the supplemental bill?

Ms. HARDY. Yes; we requested that and the reason is that so much of our dollars are needed for systems maintenance. We asked for a higher number last year, however, there was concern as to whether or not the system modernization plan was going well.

I have committed to all of you that we would not decrease staff if the cap is lifted. In other words, money would not be taken out of staff. We are committed to having full-time equivalent staffing of

63,000 next year. Any amount of dollars spent for systems after the cap is lifted would not come out of staffing.

Senator COCHRAN. Could you draw this funding from a contingency reserve if you are not granted this authority?

Mr. DYER. No; we could not. This cap of $170 million is against our whole appropriation which includes the $48 million for the contingency reserve. So we are limited under that language. That is why we would like to have the cap lifted. If those funds become available, we have flexibility where we could put them, either into automation or into staffing concerns.

Senator COCHRAN. I guess the question the committee would be interested in is whether or not you would divert funds from operations and staffing of local Social Security offices?

Mr. DYER. If we were to use any additional funds for the ITS budget, it would not come out of the staffing budget that we have now under our current operating plans.

REDUCTIONS IN RESOURCES AND MORALE

Senator COCHRAN. I know it has been a problem in many offices when you do not have enough resources to hire people that you need, when you are squeezed like you have been in terms of staffing, that puts pressure on morale, people think they are being overworked and underpaid and get mad, and has that been a problem in the agency?

Ms. HARDY. Yes; that is true. It has been somewhat of a problem, yes. Part of the way that we dealt with that is to set aside the maximum amount that we can under law for award money. So we at least have the staff working hard and the good ones are getting good bonuses at the end of each fiscal year.

In addition, we try to have a few more dollars for more terminals. Even in the offices where we have two people for one terminal, it should be one for one so that we would be even more productive. But we do not have enough dollars yet to make sure that we can get that done. Plus we have the concern that if everybody did have a terminal, we do not have enough memory and systems capacity in Baltimore to support everybody working away for 12 hours a day.

So we have come to a point with our systems where, unfortunately, we need additional dollars to support a really modern organization.

Senator COCHRAN. I am impressed that you have been able to manage as well as you have with the resource cutback that we have seen here in the program budget.

Ms. HARDY. I did point out, Senator, that had we come in this year just for the same staffing level that we had 6 years ago, we would be requesting $600 million more just for that. And clearly that would just be for salaries and not for the computers and everything else to support those people.

We figure we have saved at least $2 billion just in staffing over the last 6 years.

PAY RAISE FOR 1990

Senator COCHRAN. I think I saw in the paper this morning, too, that the Director of the Office of Management and Budget was suggesting that they were going to clear a 4-percent increase for military pay and a 2-percent increase for civilian pay just as a cost-of-living adjustment?

Ms. HARDY. That is for next year.

Senator COCHRAN. I did not really get a chance to look at it very carefully.

Ms. HARDY. That is for next year.

Senator COCHRAN. I was going to ask you what your reaction to that was and what the impact would be on agency employees?

Mr. DYER. If we have to absorb the 2-percent pay raise as currently proposed in the President's budget for civilian payroll employees, which is about $30 million for us, it would mean we would have to cut back on some of the staffing we have planned on for 1990.

Senator COCHRAN. What does that do to the budget request that is before the committee?

Mr. DYER. It stays the same because administration policy is to submit a request without the pay raise reflected in it. That is handled centrally.

NOTCH BENEFICIARIES

Senator BUMPERS. We were talking about the last year's notch babies.

Ms. HARDY. Bills that are up here range from $30 billion to $500 billion over the first 5 years. They go from, fix everybody and take everyone from the 1917 level and keep it forever to just give everybody 10 cents more and say that is it.

The two biggest questions I have are, one, we do not have the money. Although the reserves are building and despite all of the discussions about big reserves, $150 billion in the bank is only 8 months worth of benefits. That is all that is there.

Second is that, should we decide to do something about the notch, you will just create another one for everyone born after 1921.

Senator BUMPERS. It is not just that 4-year spread, everybody after that is getting treated the same as the last year babies are?

Ms. HARDY. They are getting less. Everybody after is getting less, yes.

Senator BUMPERS. It is just the ones who were born before 1917 are getting a little——

Ms. HARDY. The 1910 to 1916 beneficiaries are the windfall guys. I have tried to encourage the seniors to have a friend who is a windfall beneficiary. Clearly that does not always work, but all of the experts and the National Academy of Social Insurance and everybody else has suggested that we not try to correct for the notch.

UNEMPLOYMENT RATES AND TRUST FUND CONTRIBUTIONS

Senator BUMPERS. As a rule of thumb, what does the increase of 1 percent on the unemployment rate do to contributions?

Ms. HARDY. That one I do not know.

Senator BUMPERS. Anybody? You know that contributions, of course, drop as unemployment goes up, of course, but you do not have that figure?

Ms. HARDY. Not off the top of my head, no, sir.

Senator BUMPERS. Everybody is reporting about the fact that it is going to be about a $60 billion increase. This year I think we are taking on $1 billion more every week that we pay out in Social Security payments, but it wouldn't take long with, say, a 10-percent unemployment rate to reverse that, would it? It would have a pretty dramatic impact on that.

Ms. HARDY. That is the 8 months in the bank that I think should be higher than that, yes, sir.

Senator BUMPERS. I am surprised you do not have some kind of a ballpark figure as to what the unemployment rate does to contributions.

Mr. ENOFF. The unemployment rate interacts with other functions, particularly because the person does not get wages. But we do not pay the benefits on those wages that are not earned. You are just talking about revenues.

Senator BUMPERS. If a 1-percent unemployment rate raises the deficit by $15 billion, do you know what percentage of all of the taxes paid—it is unfair to ask you that.

Ms. HARDY. I could tell you 50 percent of America pays more to us than they do to IRS.

Senator BUMPERS. Some 50 percent of the people pay more to the Social Security Administration than they pay in taxes?

Ms. HARDY. Yes, sir.

Senator BUMPERS. That is a menacing figure to me. Well, the Armstrong amendment is a done deal; 10 brave souls voted "no" to that, so you might as well go back and get your actuarial books out to figure out what that is going to cost.

HEALTH INSURANCE TRUST FUND CONTRIBUTIONS

Finally, just one question, Can you tell me, were you here when I asked a question of Mr. Hays a moment ago about everybody paying 1½ percent on their total income? Lee Iacocca would have had to pay 1½ percent on $3½ million last year. And I think he would be happy to do it.

Ms. HARDY. Quick off the top here, we get about $10 billion for the health insurance trust fund.

Senator HARKIN. If you unlimit the cap?

Mr. ENOFF. Yes.

Ms. HARDY. Employer and employee combined.

Senator BUMPERS. That is both. That is the best and easiest way to pick up money for Medicare and the deficit of anything I can think of.

Senator HARKIN. How much did you pick up, $5 billion or $10 billion?

Ms. HARDY. About $10 billion from employers and employees, combined; $5 billion from each for health insurance.

Senator BUMPERS. This was tinkered with in the Finance Committee.

Ms. HARDY. Either Mr. Hays or we will supply that.

Senator BUMPERS. I would just like that verified.

Ms. HARDY. That was using some assumptions that I came up with that about 5 percent of the people would be affected.

Senator BUMPERS. I think we ought to continue to try to bring health care costs down in this country. I am not suggesting 4½ percent. We might use it for long-term care, which is the biggest void in health care in this country, but you are probably talking about $30 billion, and 1½ percent of them will only pay about one-third of long-term care for health care.

Catastrophic illness was a great advance, but it was just peanuts compared to what long-term care is going to cost.

Ms. Hardy, I thank you. I think that concludes all of my questions.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Ms. Hardy, thank you very much. We have other questions which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Telephone Busy Signals

Question. The Social Security Administration implemented nationwide 800 number phone service in October 1988. While the cost of the service was 50 percent higher than the old phone system, 800 service was designed to provide better service, in particular, as busy signals rates were not to exceed 5 percent. This rate represents a significant improvement over the approximately 15 percent busy rate determined by GAO in tests made in 1985 and 1988.

In January and February of this year, the weekly busy signal rate has frequently exceeded 30 percent and on one occasion has exceeded 60 percent, which is a far cry from the 5 percent promised.

What are you doing to get the busy rate down?

Answer. Efforts continue with the service contractor to refine the telephone network routing plan. By rerouting calls to teleservice centers with available capacity, improvements in busy signal rates have already been realized. Teleservice managers are also continuing to refine work schedules to insure adequate coverage during lunch periods and on peak demand days. Because of significant improvements in the busy signal rates in March, reallocation of staff from field offices to TSC was limited in April and is not planned for May.

The principal activity underway to reduce busy rates is the establishment of three, new, large (mega-site) teleservice centers and the expansion of the teleservice center in Birmingham, Alabama. The three new mega-sites will be located in Baltimore, Maryland, Albuquerque, New Mexico and Auburn, Washington and will be operating by October 1, 1989. Also, a new routing plan which more effectively distributes calls will be in effect.

Efforts are also underway to have a significant number of part-time employees in the new mega-sites. With an appropriate mix of full-time and part-time employees, we will be able to schedule adequate numbers of teleservice representatives during peak demand times to keep busy rates down.

Public information activities are also underway to educate the public about the best times to call 800 Number service. For example, busy rates are lowest during non-check weeks, on Wednesday through Friday and before 10 a.m. and after 3 p.m. A brochure with explanations on how to use the automated equipment available for simple transactions from 7 p.m. to 7 a.m. is also being prepared.

Question. Is the rate dropping?

Answer. Yes. The average busy signal rate for 800 Number service from October through December 1988 was 16.6 percent. In January and February 1989, which traditionally are very high workload periods, busy signal rates increased to an average of 38.6 percent.

In March, the rate dropped significantly to 9.3 percent--the lowest rate since 800 Number service began. The rate during the first 3 weeks in April was at about the same rate as in March. If the period around check delivery day (April 3 and April 4) is excluded, the busy rate for the first three weeks of April was actually under 8 percent. On 40 percent of the workdays from April 1 through April 21, the busy rate was 5 percent or lower.

Question. Are you still committed to providing a busy signal rate of 5 percent even if additional staff is required beyond what you had originally planned?

Answer. We are committed to reaching an average 5 percent busy rate once the National 800 Number Service is fully implemented. While we will continue to evaluate staffing needs, one advantage of a national network is that there is flexibility for utilizing resources among teleservice centers. By refining the network routing plan, calls can be routed to less busy centers to bring down the over-all rate. When the mega-sites are fully operational in each of the time zones, the routing plan can be used to maximize resources available in these offices. Hiring a significant number of part-time employees in the new mega-sites and establishing work schedules that ensure maximum coverage at peak periods will also help us reduce busy rates.

Office Waiting Times

Question. The Social Security Administration has been measuring waiting times since January 1986. The statistics show that waiting times have declined, fairly steadily, from 12.3 minutes as reported in March 1986 to 5.0 minutes as of June 1988. Now the Social Security Administration has revised its methods for measuring waiting times in fiscal year 1989, as requested by this Committee. Data for December 1988 show average wait times, as now measured, are back up to 12 minutes, and 19 minutes, if you count pre-receptioning time (the waiting period from the time clients walk in the door until they are seen by a receptionist).

Have wait times actually doubled in the last six months, or is this just a statistical change?

Answer. No, wait times have not doubled in the past 6 months. The longer measured time under the present study method is related to a technical difference in counting individuals served in "speed lines". A speed line is an interview delivery technique in which technical staff are assigned to the reception area and complete visitor business at a work station within the reception area. The speed line technique generally provides quicker service for most actions, except claims interviews.

The prior waiting time study made an assumption that no queuing occurred in speed lines. The interview was counted, but the waiting time was assumed to be zero. This measurement depressed interview waiting times.

The new waiting time study counts any queuing in speed lines as part of the prereception study measurement. Neither the interviews nor the minutes are included in interview waiting time, but both the interviews and the minutes are included in the prereception time data.

Question. Is an average wait time of 19 minutes acceptable to you?

Answer. No, we would like to see immediate service in our field offices and continually strive to provide our clients with more efficient, convenient service. We encourage the use of appointments for scheduling both face-to-face visits and teleclaims. As more people make use of this service, wait times for all will decrease. Those with appointments usually receive immediate service.

Question. What percentage of clients have to wait more than 30 minutes?

Answer. Data for the quarter ending December 1988 revealed that 9 percent of clients wait more than 30 minutes to be served. The quarter ending March 1989, shows that 8 percent of all clients served waited more than 30 minutes.

Staffing of Office of Hearings and Appeals

Question. In my State of Iowa it routinely takes six months for a disability claimant to get a hearing date scheduled. That's a half-year for low-income people to survive, while waiting to hear from your agency. Usually, they've been unemployed for several months prior to applying for disability benefits, and every day's delay compounds suffering. Clearly, justice delayed is justice denied.

How can these people be expected to support themselves and their families while waiting to hear from you and what can you do to shorten these delays?

Answer. We have already taken action to shorten the delays.

As of March 1989, the Des Moines Hearing Office, which services all but two communities in the State of Iowa, had a total of thirty full-time permanent employees, including six Administrative Law Judges, and four part-time permanent employees. We hired two of the Administrative Law Judges in fiscal year 1988 and believe that, as they gain experience, service to the residents of Iowa will improve, and the waiting time for hearings will decrease.

We also recently hired three new hearing clerks for the Des Moines office to help process cases and type decisions. Once they are fully trained, they should make a significant contribution to productivity and further reduce waiting times.

In addition to staff increases, the Des Moines office is using one of our new Word Processing Centers to type decisions.

In March, the Chief Administrative Law Judge visited the Des Moines Hearing Office to confer with the management staff and provide assistance and encouragement in their efforts to improve production and to provide more timely hearings.

The staff in our local field offices are trained to help individuals and families facing hardship find the various public and private organizations which may provide interim assistance while we process their claims. In your State, the Iowa Department of Human Services administers programs and sets eligibility guidelines for cash benefits or vouchers to assist those in need of food and shelter.

Additionally, when we become aware that a claimant is in dire need, we expedite the assignment of a hearing date and the disposition of the decision.

Views of Agency Personnel

Question. A GAO survey of Social Security Administration personnel made in the summer of 1988 shows a significant decline in service quality and employee morale when compared to a 1986 survey. Field office managers, for example, who rated their units' performance as declining quadrupled since 1986--from 11 to 47 percent. Similarly, 2 years ago, the managers felt that nearly half of their employees had high morale; in 1988 only about a quarter of the managers held this view.

What is your reaction to the GAO study?

Answer. Although the GAO report concludes that the morale of some employees and managers is low and that there is dissatisfaction with the staff reduction initiative, I believe there are also some positive and constructive interpretations to be made of the GAO data. Despite that fact that SSA, like many organizations in the public and private sector, is undergoing significant changes with restricted resources, the GAO data show that SSA employees continue to regard highly their commitment to SSA's mission and the public we serve. Also, although the GAO findings show that low morale is related to staff reductions, Agency performance indicators have generally improved over the period of time covered by the reductions in staff. Finally, the GAO report indicates that SSA employees have begun to view positively such agency initiatives as claimant appointments, teleclaims, and automation, of which they previously were skeptical, indicating normal adjustment to major change.

Question. Should the Social Security Administration be pursuing further staff reductions in 1990, particularly since these reductions were the principal reason for the perceived decline in performance and morale, according to the GAO survey?

Answer. SSA is nearing the end of its downsizing. In fact, the FY 1990 budget request assumes that, agency-wide, SSA should be able to replace most of its staffing losses in FY 1990, if the requested level of funding of $3,833,389,000 is provided in the LAE account. The reduction of 1,948 full-time equivalents in FY 1990

will result primarily from employment reductions achieved during FY 1989.

Question. GAO also found that field managers and employees believe that continuing the staff reduction effort through 1990 will adversely affect work quality, public service, and result in decreased productivity.

How do you respond to this finding?

Answer. In FY 1990, if the requested funding level of $3,833,389,000 is provided in the LAE account, SSA should be able to replace most of its staffing losses on an agency-wide basis. For FY 1990 and later, staffing should remain roughly level, agency-wide. It is also important to note that, throughout the period of the downsizing, actual indicators of performance have generally improved.

Question. What actions are you taking to improve the morale of your employees?

Answer. In response to the concerns about morale expressed in our survey of management personnel last year, we held regional management forums that gave managers and supervisors in the field, the program service centers and headquarters components the opportunity to communicate directly with the Commissioner and the Executive Staff.

These forums produced several hundred specific recommendations, which led to many actions which will improve the way we work and our service to the public. The forums also gave the Executive Staff of the agency a renewed responsiveness to the concerns of managers and supervisors at all levels.

We will continue to hold forums with managers and supervisors at least once a year to keep the lines of communication open at all levels and to ensure that managers and supervisors are integrally involved in the decisions that affect them and their employees. We are now in the process of surveying all our employees to determine where problems with communication and morale still exist.

We also place a strong emphasis on recognizing and rewarding the commitment, hard work, and dedication of our employees, through cash and honor awards, and by improving communication and employee involvement in the decisions affecting the agency.

Board and Care Homes

Question. An estimated $3 billion in Supplemental Security Income (SSI) and Social Security funds are spent annually on board and care facilities for low-income elderly, mentally ill, and disabled individuals. Recent reports by GAO and Chairman Claude Pepper of the House Subcommittee on Health and Long-Term Care have documented the deplorable conditions in many of these homes, as well as cases of outright fraud, abuse, and neglect. Even though regulations require States to submit reports to the Social Security Administration on deficient board and care homes, only four states bother to comply.

Do you believe that billions of dollars of Federal appropriations should continue to be channeled to board and care facilities without adequate public oversight on quality?

Answer. Public dollars used to purchase board and care come from the Supplemental Security Income (SSI) program and State supplements to SSI recipients. The SSI program provides cash benefits for aged, blind and disabled persons who meet a statutory test of financial need. States are permitted to supplement the basic Federal income support levels for certain groups. The Federal role in determining how SSI payments are spent is quite appropriately a limited one. In the case of board and care homes, there are two ways that Federal SSI policy has had an impact. First, the Social Security Administration is required to appoint representative payees for SSI recipients who are determined to be incapable of managing their funds. In some instances, this means that the owner/operator of a board and care home receives the check of a board and care resident. Secondly, States are required to establish and enforce standards for care in nonmedical facilities housing a significant number of SSI recipients (the Keys Amendment).

Over the past decade the board and care industry seems to have grown rapidly. It has become an important part of the continuum of services needed by people with disabilities who are unable to stay in their own homes or with their families and yet do not require the 24 hour supervision and services of a nursing home. Clearly there are instances where some board and care residents have been exposed to hazardous conditions or worse or have received inappropriate care. It is also widely agreed that the Keys amendment has not been an effective way to define a Federal role in board and care.

The problem we face is how to devise a system of public oversight which is feasible to implement and does not cause economic hardship to board and care operators who are responsibly providing a much needed service. Burdensome regulation will be self-defeating if it drives such operators out of business. Any system of public oversight of board and care must be devised and carried out at the State and local level. However, the extent to which or how State regulation or the lack of regulation results in inadequate or poor quality care for board and care recipients is not known. Unfortunately we even lack very basic information on the number of board and care homes or the characteristics of the owner operators, residents or services. Nor do we know the extent of abuse, neglect and unsafe living conditions in these facilities or what kind of public oversight is needed to improve the quality of board and care arrangements. For these reasons, the Department of Health and Human Services (DHHS) proposes to conduct an assessment of health and safety conditions and quality of care in board and care homes in a variety of regulatory climates. If this study is able to document a relationship between specific regulatory practices and living conditions of board and care residents, DHHS will be better able to help States carry out their oversight functions.

Question. What can be done administratively to strengthen monitoring of board and care facilities?

Answer. The responsibility for regulating board and care homes and developing adequate quality assurance systems lies primarily with the States. While more nationally representative data are needed to formulate specific regulatory strategies, the Department of Health and Human Services' orientation is not to impose a new Federal system but to strengthen the capacity of States in the area.

Question. Should hospitals be required to discharge Medicare patients only to licensed board and care homes?

Answer. Hospitals should have as much discretion as possible in the choice of setting regarded as most appropriate for discharged patients. The reasons why some homes are not subject to licensing vary from State to State. For example, in some States, only homes with a resident population over a certain size are subject to being licensed. Even so, smaller unlicensed homes may be providing adequate care to their residents. Unlicensed homes may provide an acceptable "spillover" option for hospitals in communities where the bed supply of licensed homes is limited. In general, licensed board and care homes may be assumed to meet minimum standards of care and safety more often than unlicensed homes. However, individual needs and care options differ widely. While discharge to licensed board and care facilities may be preferable in most cases, it should not be required.

Abuse of Representative Payee System

Question. Last fall, the press widely reported the case in Sacramento where a boarding house operator allegedly cashed Social Security checks of deceased residents--and has been charged with multiple murders. One resident who survived says he was lucky he never made the owner his representative payee.

In view of this case, do you feel there is a need to reform the representative payee system?

Answer. We should note that the landlady in the Sacramento boarding house was the representative payee for only one individual. However, SSA already had reviewed the kinds of information available under our current system and recognized the need to adapt our automated information systems to provide additional information on representative payees.

An automated data processing (ADP) plan has been prepared and approved for development. The development will begin in June, 1989. The proposed system will allow:

- o screening of the applicant at the time a representative payee application is filed to determine:

  a. if the proposed payee is representative payee for others;

  b. whether misuse has been established on any of these other records;

  c. if so, the disposition of any misuse case;

d. if the proposed payee is currently receiving his or her own benefits;

e. if so, whether overpayments have been a problem for the payee's own benefits;

f. if the proposed payee has a representative payee;

g. if the beneficiary for whom the proposed payee is filing is representative payee for others;

h. if so, a listing of those beneficiaries for new payee development,

i. if the proposed payee is a drug addict or alcoholic as defined by Supplemental Security Income regulations.

- o identification of all persons who receive payments for more than one beneficiary.
- o tracking of misuse of benefit payments.
- o production of regular and ad hoc reports.
- o collection of felony conviction information.

Specification development for the system is expected to be completed in September, 1989.

Question. How susceptible is the representative payee system to abuse, and how could program accountability be improved?

Answer. SSA plans to run a series of studies designed to identify problem areas in representative payment. The study results will be used to identify those types of payees who are most likely to have problems adequately performing their duties as representative payee.

These studies, along with the systems enhancements described previously, will allow identification of actual and potential abuses.

Question. What suggestions do you have for improving conditions at substandard board and care facilities, which are heavily dependent on an estimated $3 billion in annual Social Security and SSI payments from residents?

Answer. Board and care problems are not necessarily related to SSA representative payment issues. The Sacramento boarding house case involved 16 boarders, only 3 of whom had payees. We believe the board and care issue is best addressed by a Department of Health and Human Services (DHHS) taskforce convened on representative payment which has broad DHHS component representation, including components with direct responsibility for board and care issues.

Payments to Criminally Insane

Question. The Social Security Act requires suspension of

payments to beneficiaries convicted of a felony, and confined to jail. Yet offenders found not guilty by reason of insanity and confined to a mental institution continue to receive disability payments.

The HHS Inspector General conducted a review in three states, and found 38 percent of offenders in mental hospitals getting benefits of about $400 a month. An estimated $10.4 million could be saved annually by outlawing such benefits. Why should offenders like John Hinckley, Jr. continue to receive Social Security disability benefits? Don't the mental hospitals take care of essential expenses such as food, housing and clothing of the criminally insane?

Answer. Present law requires that we pay benefits to those who have been found not guilty by reason of insanity and are confined to mental institutions, even though their food, shelter and clothing may be provided by the mental institution in which they are confined. Although SSA may agree philosophically with a proposal to suspend benefits to such persons, there are serious legal, equity and administrative problems with the proposal. The primary difficulty is that the proposed change would give the appearance of unequal treatment, since the benefits of other institutionalized patients, who also have food, shelter and clothing provided, would not be suspended.

Office Closings

Question. Over the last five years, you have reduced staff 20 percent, but have kept office closings to normal levels, by historical standards. How many office closings do you expect in fiscal 1990?

Answer. We have made no decision to close any field offices in fiscal year 1990.

Question. Do your long-range plans for the year 2000 contemplate keeping approximately the current level of 1,300 field offices?

Answer. We expect to have roughly the same number of field offices in the year 2000, although they may have fewer people working in them.

Question. Do you expect staffing to level off at 63,000 positions in the decade following 1990?

Answer. Yes, we expect employment (full-time equivalent workyears) to stabilize after 1990 consistent with workload and productivity changes.

Question. How many program service centers and data operation centers do you expect to have in the year 2000?

Answer. We have no plans to change the number of program service centers. In July, 1988 the Office of the Inspector General, DHHS, released a report containing 4 options for the future of the Data Operations Centers (DOCs). Among those options was one

recommendation to consolidate from the current structure of 3 DOCs to 2. This is a reflection of the fact that the primary DOC workload - input of wage reports - has declined as a result of the switch to magnetic media reporting by many employers.

No decisions have been reached on these options at this time. We plan to continue reviewing our current operation to determine the most effective and efficient use of resources with an eye toward our changing workload and new technologies.

"Death Data" Not Being Shared

Question. In recent years, the Social Security Administration has been working with the states to establish accurate death records to prevent improper payments to Social Security beneficiaries. Obviously, an accurate "death tape" could be of immense value to all other Federal and Federal/state programs that pay benefits to program participants. Such a tape would be used to insure that program benefits (public assistance, railroad retirement, Medicare, etc.) are not paid to deceased individuals.

What is the status of the Social Security Administration's efforts to develop an accurate "death tape"?

Answer. Social Security Administration (SSA) death data is considered "accurate". SSA maintains its death data on the number identification (NUMIDENT) system. The NUMIDENT contains both verified and unverified death information. SSA routinely verifies only claims or benefit-related death data. SSA posts but does not routinely verify non-claims related death information. SSA will verify non-claims death data in certain situations--when earnings are credited to a social security record more than one year after the posted death of the worker, for example.

Question. How many States are sharing death certificate data with Social Security?

Answer. The Bureau of Vital Statistics (BVS) of each of the 50 States, Puerto Rico, New York City and the District of Columbia have all agreed to provide data to SSA. The last BVS will begin providing data early in 1990.

Question. To what extent is Social Security sharing this data with other Federal and State agencies?

Answer. Each of the 50 States may access death data via the Beneficiary Earnings Data Exchange (BENDEX), the State Data Exchange (SDX), and the Third-Party Query (TPQY) system.

The Health Care Financing Administration, the Office of Personnel Management, and the Railroad Retirement Board all share SSA death data. SSA has been in touch with the Department of Veterans Affairs (VA) concerning death data sharing, however, the VA does not wish to comply with the requirement that State death information be independently verified.

Question. To what extent is Social Security making State and other Federal agencies aware of the fact that it has this data?

Answer. Section 205(r)(3) of the Social Security Act states, in part, "In the case of individuals with respect to whom Federally funded benefits are provided by (or through) a Federal or State agency other than under this Act, the Secretary shall to the extent feasible provide such information through a cooperative arrangement with such agency, for ensuring proper payment of those benefits with respect to such individuals."

Most of the Federal agencies paying a benefit payment and maintaining a beneficiary roll have already entered into a "cooperative arrangement" with SSA. Each State already has access to death data via an information exchange.

Question. What more needs to be done to get this system to work better?

Answer. A possible impediment for some agencies may be the requirement that State death data obtained from SSA records must be independently verified. This requirement is found in the contract that SSA has entered into with each of the 50 States. It should be noted, however, that State-supplied data comprise less than 5 per cent of SSA's total death information database.

SSA has conducted pilot studies to assess the feasibility of States accessing the SSA's Master Beneficiary Record and Supplemental Security Record systems via on-line computer terminals. The pilot studies proved successful and SSA is currently providing on-line access to State Social Services offices in Tennessee and will soon be providing access to offices in California. Conceivably, each of the 50 States may someday have on-line access to these records.

Social Security Computers

Question. We have been told that the Social Security Administration may be launching a massive new build-up of computer capacity, representing a ten-fold increase over the next eight years, and costing as much as $500 million over current estimates. Please comment on your long-range computer plans.

Answer. SSA has a vision of the type of public service we will be asked to provide in the year 2000. We know some of the techniques which will help provide that service. Those are described in our Strategic Plan. The report which we submitted to you in March describes the support we need to continue moving in that direction.

SSA has a variety of documents describing how we will execute various automation projects which move us toward that long-range vision as well as improve today's service. Those projects are parts of an overall, coordinated planning process. That process is also described in our March report to your committee.

Your question refers to our need for a significant increase in computing power over the next few years. Part of that need relates

to sheer volume - about 5 million more beneficiaries and recipients of Social Security programs in the year 2000 than in 1990. Part of the increase relates to new software designed to improve service in a wide variety of ways. We can quantify the rest of the increase fairly well for the next year or so because some of the software is running in pilot offices now and the only thing stopping national implementation is insufficient capacity to support the software. The projected increase after that will depend on which projects we have enough resources to undertake and how long it takes us to complete them. The scheduling of those projects is part of the coordinated planning process described in the March report.

That process considers the relationships between available work-power, systems computing power, equipment availability benefit to the public, and other similar factors as a project moves from one stage of development to another. Obviously, the budget we have to work with determines what we can undertake, and thus, to some extent, the quality of our service.

Question. Is your request for a supplemental bill language change an initial component of this long-range build-up, or simply related to immediate short-term needs?

Answer. The supplemental bill language request will enable SSA to obligate funds for critical ITS projects. The Information Technology Systems budget request includes funds in FY 1989 and FY 1990 to upgrade and begin to expand current computer capacity. These amounts will address SSA's immediate need for additional capacity to support current workloads and expansion of the 800 number service scheduled for October 1989.

Question. How much more do you expect to spend on Information Technology Systems in fiscal 1989, if we approve your supplemental bill language request?

Answer. Although the original FY 1989 President's Budget requested $220 million for Information Technology Systems obligations, the final appropriation was $168 million. Due to the carryover of $4.8 million in unobligated funds from FY 1988 and estimated recoveries of $15 million from prior years, SSA will be able to obligate up to $188 million in FY 1989 unless the cap on ITS spending is removed. This estimate is higher than the $178 million included in the January budget request because of a higher level of recoveries since that time. SSA has enough projects under review to spend at least $220 million but the actual level of spending will depend on the availability of funds.

Modernization Plan

Question. For several years now, the Committee has been waiting for SSA to develop a credible plan for managing its enormous data processing and telecommunications resources. Last year SSA was asked for a special report containing a comprehensive, detailed discussion of the agency's immediate, short-term, and long-term modernization plans and related ADP expenditures. Although the report you sent the Committee in March 1989 relates your fiscal year 1990 budget request to the agency strategic plan--SSA 2000, it is

neither comprehensive, nor complete. Your response for the record to the following questions will assist the Committee in its deliberations over SSA's FY-1990 budget and FY-1989 supplemental requests.

Has SSA developed a comprehensive, detailed data processing and telecommunications plan?

Answer. SSA has a series of planning mechanisms in place to provide for its telecommunications and data processing needs. The guiding document is the Strategic Plan which sets the course the Agency wishes to follow. To manage its software development process, SSA uses the Automated Data Processing Plan. Other plans address particular long-range projects. For instance, to manage the ongoing need to improve and maintain most of the service delivery efforts begun under the Systems Modernization Plan, it uses the Program Benefits Project Management Plan. Hardware requirements are guided by SSA's Capacity Planning and Management Systems. Current management improvement activities are reflected in the Office Automation Plan and plans for the national 800 number are in place to achieve that goal. The Information Resource Management Process being built now pulls the elements of the other processes together.

The sum of these plans provide a comprehensive planning process for SSA's data processing and telecommunications operations. Each maps to the ITS budget process to ensure that realistic funding requests are submitted and that executive level decision-making is facilitated. The plans undergo intensive cross review and coordination within the Agency to insure consistency of approach and integration. For example, our software development components prepare project plans for each major modernized software application. They show the functionality of the software and timetables for implementation.

The software plans are used by our systems operations components to refine raw capacity projections into actual machine requirements. Workloads analysis planning translates SSA business units into the amount of millions of instructions per second (MIPS) required to support these applications. Resulting plans depict the hardware configurations that will allow systems operations to most effectively yield the amount of necessary capacity.

All of these comprehensive, detailed plans are key elements in our ability to forecast and deliver future data processing requirements that will meet the needs of the Agency and the customers it serves.

Question. Is the plan predicated on an analysis of specific functional needs, or operational requirements? (Please list them in priority order.)

Answer. All of SSA's plans derive from specific functional needs relating to the business services SSA performs, i.e., enumeration, earnings record maintenance, claims, and maintenance of the rolls. A prioritization of those would be misleading since all are defined by law and all are services which must be simultaneously performed. SSA is in the business of issuing SSNs to one customer

group, while creating and maintaining correct earnings information for another customer group. SSA also processes applications for several types of benefits for one customer base while also maintaining and adjusting the payment amounts for millions of already entitled individuals. These activities differ in the portion of the public they affect at any one time. They differ in the level of public contact required, in the amount of record keeping involved, in the degree of automation already in place and in the level of impact which occurs if those activities are not carried out appropriately.

SSA's service level and operational requirements reflect the basic facts that a great many interrelated tasks need to be performed correctly, the results must meet a variety of customer's requirements and we must perform the tasks as efficiently as possible. All of these priorities affect the type of equipment we use, the way we store data, the schedules we set for software improvements and the costs of day-to-day operation of existing systems.

In a less global meaning, each automation initiative is documented by a requirements analysis which considers such things as process requirements, service level requirements, security and privacy requirements, alternative design choices, capacity impact, etc. All major initiatives conform to SSA's software design lifecycle as defined in our Software Engineering Technology Manual.

Question. Which needs or requirements cannot be satisfied by the current system?

Answer. There are many processes by which SSA uses automation to issue and maintain SSNs, to collect and maintain earnings information, to take claims and make entitlement determinations and to maintain correct payment amounts. These share several levels of needs or requirements which cannot be satisfied by today's systems.

The first need is to maintain service at today's levels. Just to maintain today's level of service with a growing base of taxpayers and beneficiaries will require more computer processing power, more data storage capacity, and more telecommunications costs. In the same vein, every year some equipment must be repaired or occasionally replaced to maintain current service levels. Computers require specialized maintenance and more of it. Those are skills SSA contracts for so they appear in our maintenance budget. A related ongoing cost reflects the price of modern business. To serve the public in every part of the United States, SSA must pay for telecommunications services. These costs directly relate to the amount of service we can provide. The SSA budget reflects these ongoing automation costs and without that floor of support, the "current system" will not only fail to maintain today's levels of service, but ultimately fail completely.

The second set of needs and requirements relates to the need to deliver the automation improvements we have ready today. We have several projects like the Manual Adjustment Credit and Awards Direct Entry (MACADE), a modernized postentitlement data entry and online edit software, already in operational pilot offices. We have proved that they reduce processing time and improve accuracy. We can't

expand them without additional capacity. Without that capacity we can't implement changes which will allow our field office representatives to check the status of a beneficiary's records without spending costly time moving between two computer systems. We also need to be able to implement the modern notice language which is ready and waiting.

The third set of needs deals with improvements we are just beginning to plan. We must provide the same improvements for the SSI program as we have done for the Retirement and Survivors Insurance programs. We must make our earnings programs work faster and make the data more accessible for correction and use. We need to improve administrative record keeping, especially for our field offices.

The fourth primary service level relates to meeting new customer requirements. These come to SSA as new laws which require systems support. There are laws which affect SSA directly and laws under which SSA must support other agencies. For example, SSA's Enumeration at Birth project supports the IRS requirement for children to have SSNs at an earlier age, and the Immigration Reform and Control Act which requires issuing SSNs to new categories of people and correcting thousands of earnings reports. New customer requirements also come from the public. They come from taxpayers who demand that their wages be credited more and more timely. They come from beneficiaries who want SSA to answer questions about their checks when they call SSA. They expect SSA to have that ability like other service organizations do rather than waiting weeks for mail responses. They expect services like the Personalized Earnings and Benefit Estimate Statement.

These types of customer requirements usually require some portion of automation support in the current system. We need to have the ability to deliver this support when it is required.

Question. To the individual Social Security recipient or client, what will be the specific consequence of not satisfying each need?

Answer. Examples of service deterioration that can occur include:

Applicants for benefits will experience longer waits for payments, both for initial claims and for adjustments to benefits. Delays could effect payment increases that some beneficiaries receive each year because of additional earnings

SSA might not be able to deliver Social Security cards to newborn infants through the Enumeration at Birth process, forcing millions of parents each year to apply for numbers by visiting their local office. Related increases in backlogs and waiting time would occur, both for those individuals and the thousands of others who visit our offices for services where face-to-face contact is actually needed.

SSA could experience an increase in lost checks or delayed checks because addresses cannot be changed timely. These produce

more work trying to straighten out problems and handle inquiries that could have been avoided in the first place.

Backlogs would increase in several post-adjudicative areas. Resulting overpayments and underpayments cause the additional work of notifying beneficiaries, collecting, extending "due process" rights, revising records, etc. All these activities cause public dissatisfaction and are very labor intensive for SSA.

If the existing capacity is not upgraded, when people call the national 800 number or their local offices, computer response time will be slow, resulting in longer waits for the caller, and increased telephone costs to SSA.

If computer capacity is not increased, SSA will not be able to modernize its SSI software, resulting in less ability to serve the most needy of our clients. If additional terminals cannot be provided to our field offices for our SSI claims representatives and service representatives, they will not be able even to use existing software as efficiently as possible.

Automation provides an overall support for the services which SSA provides. No number of dedicated, well-trained employees can perform the routine tasks which computers do so well. It would not be efficient for SSA to use people to check the dates of death in State records against those reported to us. Computers can do this and help prevent millions of dollars of overpayments. If SSA doesn't do this using computers, the taxpayers will bear the burden of either the overpayments costs to the Trust Funds or the personnel costs to accomplish physical searches of the records. There are similar trade-offs in every area.

Question. What are the specific unmet needs or requirements that will be satisfied by appropriation of the ITS funds requested in the FY-1990 budget and FY-1989 supplemental?

Answer. No additional appropriation of funds is required in FY 1989. The supplemental bill language request would permit SSA to use contingency reserve funds already appropriated on additional ITS projects. In FY 1989, SSA would spend additional funds made available for ITS on the following major projects:

- Additional terminals in the field offices for use in the automated claims-taking process;
- Personal computers (office automation workstations) throughout the agency for automation of labor intensive paper processes;
- Replacement of outmoded telephone equipment; and
- Development of new and efficient software systems to support SSA programs.

In FY 1990, over $160 million of SSA's $203 million ITS request is needed for mandatory costs. The remainder will be used for key systems and telephone enhancements including capacity increases, office automation, software support services and additional TAP terminals.

Supplemental Request

Question. You are asking for supplemental bill language to increase computer spending over the $170 million ceiling established in the FY 1989 Appropriations bill. How much more do you estimate will be needed, and when will you need this authority?

Answer. The supplemental bill language would allow SSA to spend funds already appropriated in FY 1989 on additional ITS projects. The FY 1989 President's Budget request (in January 1988) asked for $220 million for ITS expenditures, $32 million more than the amount currently estimated to be available ($188 million). We estimate that at least that amount is needed for projects already approved within SSA but not funded. Because many ITS procurements require significant lead times, the authority to obligate funds for ITS is needed as soon as possible in order to ensure that projects can be awarded by the end of the fiscal year.

Question. Can you assure us that you will not divert funds from operations and staffing of local Social Security offices, and instead, draw what you need from the contingency reserve?

Answer. Any increase in funding for telephones or computers will not cause a reduction in employment below currently planned levels in order to finance additional ITS investments in 1989.

Question. What will be the impact of Congress not approving your supplemental bill language request?

Answer. If the cap on ITS spending is not lifted, SSA will have limited ITS funds available to spend on systems enhancements. Since approximately $145 million is needed in FY 1989 for "mandatory" costs required to maintain current operations, only about $43 million (of the $188 million currently estimated to be available) can be spent on systems enhancements. SSA has identified the need in FY 1989 for at least $75 million for systems enhancement projects. If the authority to spend funds already appropriated in the contingency is not approved, many enhancements must be deferred. Major among these are high-speed printers for beneficiary notices, additional terminals for taking and processing claims and inquiries, personal computer workstations, replacement of outmoded telephone equipment and development of modernized software.

Question. Provide a detailed breakdown of how SSA will spend remaining fiscal year 1989 ITS funds and the requested supplemental appropriation. What specific service needs will be met?

Answer. SSA plans to obligate about $188 million on ITS projects in FY 1989 with resources now available. This amount consists of $168 million in new budget authority, $4.8 million in carryover of unobligated funds and an estimated $15 million in recoveries of prior year obligations. This amount is about $10 million higher than the estimate included in the January budget request.

Of the $188 million, about $145 million covers SSA's mandatory costs including telephone bills, and ongoing lease, maintenance and supply costs. If supplemental appropriations language is approved, SSA will be able to spend already-appropriated funds on additional ITS projects. The major areas that could be funded include additional terminals in field offices (to speed up the claims and inquiry process), personal computers (to automate labor-intensive administrative functions), replacement of outmoded telephone equipment (to enhance communications) and development of modern software (to simplify the administration of SSA's programs).

HCFA Program

Question. We understand you are presently processing a Health Care Financing Administration program referred to as HI-SMI on your data processing equipment and that you are reimbursed $12 million annually for this activity. In fiscal year 1990, the Health Care Financing Administration plans to move this activity to its own data processing equipment. Have you eliminated this $12 million from your fiscal year 1990 budget? If not, why not?

Answer. Because the SSA and Medicare programs traditionally have been so closely related, SSA processes various HI/SMI automated data processing and telecommunications workloads under programs administered by HCFA. Under HCFA's proposal, some of these workloads would be transferred to a HCFA computer center. The amounts charged annually to the HI and SMI trust funds represent HCFA's share of the cost of processing all trust fund work, and are allocated to the HI and SMI trust funds based on approved cost allocation methods.

SSA's budget request for Information Technology Systems (ITS) includes amounts for lease and maintenance costs of hardware, software and telecommunications services. Because SSA's requirements are based on its peak processing needs (on-line, daytime processing) and most of the HCFA work is done on off-peak (nighttime) hours, transfer of some of those workloads to a HCFA site will not have a significant impact on the fixed costs in SSA's ITS budget. SSA will still have to pay for the annual lease, maintenance and other costs to maintain its hardware and software capacity. Unless SSA can find another Agency with needs to match the available night-time hours that will become available, it is likely that the social security programs will have to absorb most of the costs.

Modernization Costs and Benefits

Question. What is the projected total cost of modernizing the SSA system? (Include costs incurred since the beginning of SSA's system modernization effort.)

Answer. Cumulative costs for the systems modernization plan (SMP) for FY 1982 through FY 1988 were about $460 million. This amount includes $385.4 million for automated data processing and telecommunications equipment and contractual services, which are a part of SSA's Information Technology Services (ITS) budget. The remaining amount of $74.6 million in estimated SMP expenditures represents the estimated costs for personnel, training, supplies and travel associated with executing the SMP. A summary by year of total

SMP expenditures, including ITS, personnel and other costs, is shown in the chart below:

Fiscal Year	Dollars (Millions)
1982	$ 8.5
1983	$ 33.2
1984	$ 57.6
1985	$ 69.3
1986	$ 113.7
1987	$ 87.6
1988	$ 90.1
Total	$460.0

Question. You have approved a new strategy that if carried out as planned will increase SSA's system capacity ten-fold. Is the population of service recipients increasing at a comparable pace?

Answer. While not a ten-fold increase, there will be a 5 million person increase in the number of beneficiaries and recipients SSA must serve between now and the Year 2000. The number of taxpayers for whom individual earnings records must be kept will also increase and the number of years a person remains as a beneficiary is increasing, with a commensurate increase in the number of postentitlement contacts. Thus, these increasing workloads do account for a portion of the capacity increase requirements.

The remaining capacity needs are based on actual current measures and modeling efforts which meet industry standards. We employ the latest industry proven testing and modeling techniques to develop our projects. We have formally documented procedures in the Software Engineering Technology manual to guide capacity planning throughout the systems development life cycle.

An independent consultant was brought in to review our capacity management program. Their first analysis, which focused on the process itself, indicated that SSA's capacity planning was very mature, better than most large data centers in either the public or private sectors and in several respects more advanced than many major organizations. The consultant returned for a subsequent review to focus on our actual capacity estimates. They determined that our projections were sound and based on good forecasting principles.

Our most recent capacity projections indicate that we will require 442 million instructions per second (MIPS) of computer capacity by October 1989 to simply support our existing workloads and expansion of 800 teleservice. These projections are based on the most reliable data available--actual experience with current workloads. Our existing base of programmatic capacity is 356 MIPS. Without immediate upgrades, our entire operation is at risk. Inadequate computer capacity will ultimately result in degradation. We constantly monitor the utilization and performance of our systems. On peak days when computer utilization is extremely high, we have

witnessed slower response times for online network systems. When this happens, customers filing a claim or making an inquiry at field offices will lose valuable time because it takes longer to process their request.

It is important to emphasize that this sizeable capacity increase will only allow SSA to continue its current operations with existing software. Several new applications have been developed and are running in a small number of pilot offices. Applications such as MACADE, MES and CICS queries could be fully implemented now if we had adequate capacity. The limited implementation of these applications has already demonstrated savings to the Agency. These software applications, like our current national workloads, have been fully modeled and tested and we have actual resource utilization data from which highly reliable capacity requirements can be projected. We estimate that 541 MIPS would be required in October 1989 to support current workloads and nationwide implementation of these pilot applications.

In addition to the service needs these applications would fulfill, there is a critical operational requirement to convert all query workloads from the older less reliable INTERCOMM software to the newer industry standard CICS software facility. Vendor support for INTERCOMM is very costly and will soon be unavailable. Processing online transactions through INTERCOMM is an ineffective use of computer resources and is prone to many operational problems as workload volumes increase.

Software is now under development which will enhance the functionality of Program Benefits, improve debt collection, modernize the earnings process and continue conversion of additional INTERCOMM query workloads. Many of these applications will be ready for implementation between now and December 1990. Our most recent capacity projections indicate that we will need 885 MIPS of computer capacity by October 1990 to support the workloads already discussed plus a major portion of the planned software now under development. Capacity needs beyond that will be determined by what projects we have the resources to undertake. The projection of a 10-fold increase is based on industry experience to date. Until the software is developed and actually modeled, it is not possible to say what our actual need will be in any year. The Federal procurement process, of course, will require that we prepare thorough justification for any increases we need.

Question. What specific needs will be met by the addition of this new capacity, and at what price?

Answer. In a few offices, SSA is currently operating some modernized software applications in pilot mode. These applications cannot be expanded nationally because of insufficient capacity. The interim approach of acquiring several new computers through a definite quantity procurement would allow the Agency to move forward with expansion of this piloted software. These software applications are ready to be utilized. They will decrease processing time and increase accuracy - resulting in lower cost to SSA and the Trust Fund.

There are even more improvements undergoing development. They include future releases of Program Benefits software, modernized earnings systems and debt management. There will certainly be additional new Agency initiatives and legislative changes that will require ADP support. The Programmatic Capacity Increase, a project designed to increase mainframe capacity for programs, is intended to fulfill these needs. The indefinite quantity feature of this procurement is the cornerstone in SSA's strategy to meet long term data processing requirements. Our long range workloads and requirements are difficult to project. The requirements we have derived for years beyond fiscal year 1990 are based on standardized growth rates and acceptable levels of computer utilization to support anticipated workload volumes. Each stage of capacity enhancement will be fully evaluated during the usual procurement justification processes. Clearly, a ten-fold increase will not be needed overnight; however, now we need to plan for future needs.

Technology costs change rapidly. Some of the improvements interact with each other so costs are difficult to partition neatly. For instance, personal computers are used in our field offices for some SSI computations as well as functions such as preparing letters to beneficiaries. Terminals purchased under the Terminal Acquisition Project are used by field offices to take claims. In other offices they are used to correct earnings records. In still others, they are used to help our teleservice representatives look at the clients records to answer questions about payment amounts.

Question. If HHS Office of Inspector General data indicate that 87 percent of the public are satisfied with the current level of service why does SSA need to acquire so much additional capacity to improve service to the 13 percent of the public that are dissatisfied?

Answer. It's not surprising that the majority of people who contact SSA are satisfied. We have always stressed courteous, prompt service and our tools for providing this are getting better. Most of the areas where the public has frequent personal contact with SSA have been improved considerably in the past few years. These areas include the retirement and disability claims taking process, the processes by which SSA assigns Social Security numbers and issues Social Security cards, the content of many of our notices and the service available to those who do business with us by phone. All of our local offices have some modern computer terminals which provide some of our employees with access to modernized data bases and thus a better ability to provide the public with accurate, efficient service.

It's time now to look at what SSA still needs to deal with--those things which neither you, nor we, nor the public are satisfied with. We are beginning to plan for the overhaul of the Supplemental Security Income software. This will require that our field office personnel who deal with SSI applicants have terminals. The new software will require more computer power. It's also time for SSA to correct the software in the retirement and disability programs which is invisible to the public. As our earlier report stated, in the last 7 years systems used for maintaining the beneficiary rolls have

been improved considerably. We are now finally at the point in our modernization scenarios that we need to improve the efficiency of those postentitlement systems so that we can significantly improve the millions of paper intensive actions we process yearly. These are in areas which support actions such as representative payee accounting and overpayment prevention. We also need to revise the processes by which we maintain and use earnings information in order to be sure we never again have to do large-scale retroactive reconciliations of wages with IRS.

We need to complete the modernization of our accounting and debt management systems to ensure that we identify, control, and collect debts owed to the Trust Funds. All of these activities are in various stages of planning at this point.

All of these activities will require computer capacity and telecommunications support. It is not clear at this point what year each of these actions will require computer resources since most of these improvements are not scheduled for implementation in the next 2 years. Past experience indicates a steady increase in required computer capacity will occur over the next few years. Some of it will occur because of the growth in the number of people we serve. Some will occur because we must bring the less visible parts of our software up-to-date.

Toll-Free Service

Question. Where will the staff for the 800 number (toll-free) service centers come from?

Answer. Approximately 1,100 full- and part-time telephone service representatives (TSRs) will be hired to help staff the four mega-teleservice centers located in Baltimore, MD, Auburn, WA, Albuquerque, NM, and Birmingham, AL.

These 1,100 TSRs will be a mix of new hires, voluntary reassignments, and internal promotions. There will be no involuntary transfers to the teleservice centers (TSC) from the Field Offices. Field Office employees may apply for TSC positions if they wish to be considered.

Quality of Teleservice Staff

Question. How much training do teleservice representatives receive?

Answer. The training program for newly hired Telephone Service Representatives (TSRs) is the same as for employees who are promoted or reassigned to the job from other Social Security Administration (SSA) components.

TSRs receive eight weeks of classroom training, plus on-the-job training. In addition, trainees are assisted by technical advisors, experienced TSRs and supervisors for up to three years. The training course is the same as that received by Service Representatives in the Field Offices.

TSRs are trained on SSA program rules and regulations, special Teleservice Center operating procedures and specially designed computer screens which provide access to several online data bases.

Question. Do you have a problem recruiting and retaining high quality staff for these teleservice centers? I understand you only pay telephone representatives at the GS-7 level, which is only $20,000 per year. Is this enough money to attract people with sufficient ability to absorb and interpret complex Social Security laws?

Answer. These two issues are so closely related I would like to address them together. In the past, we have been able to recruit high quality staff because most sites were relatively small and we did not need to recruit a large number of employees. In fiscal year 1988, teleservice centers had an attrition rate of 18.3 percent which resulted in having to replace experienced staff with new staff. There are indicators that it may be difficult to recruit in some locations. The problem of retaining high quality staff is attributable to Federal salary levels and is not unique to SSA.

Duplicate Social Security Payments

Question. The HHS Inspector General's office maintains that the Social Security Administration's internal controls are not as effective as they could be in identifying overpayment. A report issued a year ago said you could identify $2.7 million in overpayments and realize savings of $612,000 over a 12-month period, by utilizing computer programs developed by the Inspector General's Office to identify multiple payments to the same person. Have you indeed been able to achieve these savings in the Old-Age and Survivors Insurance Program?

Answer. Since the Office of Inspector General (OIG) recommended that its computer program for detecting multiple payments be incorporated into existing internal controls, a sample test has been run at the Mid-Atlantic Program Service Center in Philadelphia. The findings of the test are now being reviewed and evaluated. We expect a decision as to whether or not to incorporate the OIG software by May 31, 1989.

Multiple payment situations identified in the OIG sample have been processed to terminate the multiple payments and attempt recovery of overpayments where appropriate. However, the overpaid amounts to which you refer are projections based on that small sample. Until the OIG software or another systems modification is incorporated into existing internal controls, at least some of these overpayments likely will remain undetected.

Question. What procedures are in place to identify and correct situations where beneficiaries are receiving unauthorized benefit payments?

Answer. The Social Security Administration (SSA) uses many techniques to curtail fraud and abuse. The major systems operation aimed at avoiding multiple payments to the same person is the Master File Duplicate Detection Operation (MAFDUP). The MAFDUP, which is

run twice annually, identifies match situations in which the same name, month and year of birth, and ZIP code are used. Identified cases must then be manually checked to verify that both records relate to the same beneficiary and that an improper payment is being made. Some persons properly receive more than one check.

The software developed for this audit by the Office of Inspector General staff identifies additional cases not detected by the MATDUP, which requires an exact match of full names and other identifying information.

Recovering Moneys Owed the Trust Funds Long After Short Term Collection Actions Prove to Be Unproductive

Question. Between 1988 and 1997, the Health and Human Services Inspector General estimated that over $60 million in debts owed to the Social Security Administration by former beneficiaries would be written off each year. The only recovery option available once benefits paid by the Administration have ended and collection efforts have proven unproductive is to offset the debts against benefits that will be paid in the distant future when reentitlement occurs.

To what extent does the Social Security Administration inform debtors about the time value of money and how interest charges will cause their debts to grow significantly if their debts are not repaid?

Answer. The Social Security Administration (SSA) does not furnish its overpaid beneficiaries with information concerning money's loss in value over time or the impact the imposition of interest would have on their debt. Because our collection efforts seek to recover only the amount overpaid, providing such information would give overpaid persons one more reason to avoid prompt repayment.

The SSA policy on charging interest on overpayments continues to be guided by a December 1982 letter from the Chairman of the House Ways and Means Committee in which he stated his views on SSA's debt collection activities, and in his final sentence concluded, "The House amendment to H.R. 4613 [the bill which became the Debt Collection Act of 1982] exempting Social Security Act programs from these provisions of the bill was therefore quite specifically intended to forestall the Social Security Administration from using collection agencies, charging interest on overpayments, and offsetting against social security benefits overpayments in other programs."

Although the Office of Inspector General report recommended that SSA adopt a policy of collecting the higher of (a) the interest income lost to the trust funds, or (b) the value lost to the trust funds due to inflation, we believe that our statutory authority to institute such a policy is not clear, and we would decline to institute such changes without a legislative mandate from the Congress.

Measures of Service Quality

Question. Measures of your Agency's performance that are routinely reported to this Committee have a heavy emphasis on the accuracy and timeliness of initial claim processing. Recognizing that the Social Security Administration performs many other valuable services, GAO has cited a need to develop more comprehensive measures of performance and service quality.

Do you have any ongoing activities directed to improving your performance measures?

Answer. Several actions that we have initiated recently are providing us with better information on our performance with nonclaims activities, as well as with initial claims. Each year, SSA conducts special studies of selected processes. These studies generally focus on nonclaims activities and often concentrate on service to the public. For example, we recently conducted special reviews of the new 800 telephone number and the Personal Earnings and Benefit Estimate Statement (PEBES).

In an effort to improve the reliability of the counts of the workloads we handle, we implemented an automated workload measurement system on October 1, 1988 that replaced our previous system of manual counts. Of the approximately 40 workloads automatically counted, 31 are nonclaims activities.

While these and other efforts improve performance in nonclaims activity, there are several reasons we have more performance measures already in place for claims. For one, claims are entered into our automated systems when applications are made, and thus definite processing time data can be tracked and developed. Some nonclaims activities do not result in a systems input and are, therefore, not prone to automated tracking. In addition, claims processing generally extends over some period of time as proofs and development actions are handled, and thus processing time is a meaningful measure. For many nonclaims activities, the event is of an immediate nature (i.e., answering a question) and, therefore, not subject to time measurement. In order to improve service to the public, several major postentitlement activities are handled "on-the-spot". We do, of course, monitor all situations in which there is a potential for workload buildup.

Even with these concerns, we will continue to make improvements in our performance measurement.

Question. What additional performance measures are you considering, and when might we expect to start seeing some data?

Answer. In fiscal year 1989, SSA began a new quality review program called integrated reviews. This new program places more emphasis on preventing payment error. Both personal contact and folder review are part of this process. Our initial efforts involve claims activity. However, we are currently piloting a program to extend this concept to postentitlement activities and expect to begin a postentitlement review in FY 1990.

In addition to this effort, we evaluate each automation enhancement in SSA to determine opportunities for improved management information and performance measures on our workload. The more of our processes that are automated, the wider range the of nonclaims activities that will be accurately tracked and measured.

Supplemental Security Income (SSI) Outreach for Homeless Individuals

Question. In the recent past, the Social Security Administration (SSA) embarked on a number of demonstrations aimed at providing information to and determining the SSI eligibility of homeless individuals. Were these demonstrations successful? What was the outcome? Were SSA staff stationed at shelters for the homeless?

Answer. SSA has a variety of outreach efforts to the homeless, geared to the needs and resources of specific communities. SSA's outreach efforts with regard to the homeless include:

- appointing a homeless coordinator to be the focal point for establishing a referral procedure and acting as liaison in each field office where such a position would be appropriate;
- encouraging district and branch managers or other appropriate field office staff to serve on interagency health and welfare councils serving the needs of the homeless;
- assuring that all appropriate individuals are aware of the relatively new provision for continued receipt of full SSI benefits for certain individuals temporarily institutionalized in public or private medical facilities;
- publicizing to shelters the relatively new provision for continued receipt of SSI benefits for 6 months in any consecutive 9-month period for persons who are residents of public emergency shelters;
- assuring that appropriate individuals are aware that there is no offset against SSI benefits because of receipt of charitable gifts based on need, from nonprofit organizations of items such as meals from soup kitchens, clothing and shelter;
- assuring that local staff "network" with private nonprofit community and religious organizations serving the needs of the homeless; and
- preparing a series of "best practices" issuances which describe projects dealing with the homeless and other categories of hard-to-reach people which are working well in one setting and have the potential for proving

successful in another. These issuances should allow SSA offices and other service providers to give active consideration to practices that have already been proven in other areas.

One example of a successful outreach effort is the St. Francis House Outreach Project in Boston, Massachusetts. Once a week staff from SSA's Boston district office visit St. Francis House, which serves as a day shelter for the homeless, to take claims and handle postentitlement actions. Disability determinations are made by a special unit in the State Disability Determination Unit and consultative examinations for psychological disabilities are held onsite at St. Francis House. This project has been extremely successful in serving the needs of the homeless and processing claims efficiently and quickly. Other district offices in the Boston region are exploring similar arrangements, and the project now has been shared with all regions as a "best practice."

Question. What share of homeless persons receive SSI?

Answer. Since estimates of the number of homeless individuals vary considerably, and since homelessness is not a condition of eligibility, SSA does not have the information available to answer this question.

Supplemental Security Income (SSI) Vocational Rehabilitation

Question. Under SSI law, the Social Security Administration reimburses the State vocational rehabilitation (VR) agencies for costs incurred in successfully rehabilitating SSI recipients. (VR agencies also are reimbursed for SSI recipients who refuse to continue services and lose their SSI benefits as a result.) A successful rehabilitation is defined by law as one in which vocational rehabilitation services result in performance of substantial gainful activity for a continuous period of 9 months. How many SSI recipients were "rehabilitated" over the last several years?

Answer. A "rehabilitation" period lasts about 3 years on average. After rehabilitation, SSA receives a reimbursement claim which is then processed in order of receipt. The following table summarizes the numbers of SSI Vocational Rehabilitation (VR) reimbursement claims approved for successful rehabilitations over the last several years.

Fiscal Year	Approved Reimbursements SSI Rehabilitations
1983	3
1984	652
1985	738
1986	1,310
1987	1,678
1988	2,183

Question. How much did it cost?

Answer. The following table summarizes the cost of the SSI Vocational Rehabilitation (VR) program over the last several years:

Fiscal Year	SSI Award Costs
1983	$ 4,422
1984	$ 1,276,301
1985	$ 2,106,994
1986	$ 7,510,206
1987	$11,253,762
1988	$14,487,515

Question. Is the VR program for SSI recipients considered successful?

Answer. Yes, the VR program for SSI recipients is considered successful. Only those rehabilitations deemed to be successful by our definition of 9 months substantial gainful activity are considered for reimbursement. In determining the amount to be reimbursed to any State, each case is limited to how much will ultimately be saved in general revenues by removal of this person from the benefit rolls.

Question. It has been reported that in October 1988 the Social Security Administration revised it methods of reimbursements to States for VR and that those changes are expected to result in a 20 percent reduction in the average payment per rehabilitation by fiscal year 1990. Is this true?

Answer. Yes, it is true that SSA revised its reimbursement formula options in a way that is expected to result in a 20 percent reduction in average payments per rehabilitation, but not until the end of fiscal year 1991.

Question. What changes did the Social Security Administration make?

Answer: One of the four formula options available for State selection prior to October 1988 was found to overstate indirect costs significantly, so this option was replaced with a more accurate option.

In addition, SSA has updated the cost/benefit analysis procedure used in calculating expected savings to the trust fund or general revenues, to include factors of age, sex, work history and average time on the rolls to provide a "cap" for high cost claims. For example, if we have a reimbursement claim for $20,000 and the analysis determines only $10,000 in savings to general revenues, SSA will award only the $10,000.

The changes are effective only for claims in which VR services ended after September 1988. Because the continuous period of SGA is usually not completed until about seven months after VR services end, SSA expects to continue receiving claims using the old formula option and cost/benefit analysis well into FY 1989. Also, due to current

backlogs and the volume of claims received, some cases sent to SSA using the old option and analysis will possibly not be cleared until the end of FY 1990, so the full effect of the changes are not expected to be realized until FY 1991.

Savings from Disability Rolls

Question. Your budget shows that $23.5 billion will be paid to 4,136,000 individuals under the disability insurance program in FY 1990. This represents an increase of $1.2 billion over FY 1989 costs.

Are there ways we can save money by doing a better job rehabilitating injured workers, instead of perpetuating them on the disability rolls?

Answer. Yes, I believe there are ways we can save money by doing a better job rehabilitating injured workers. In fact SSA has a major initiative underway in which we are developing, testing, and implementing new and innovative techniques to assist and encourage disabled Social Security beneficiaries and disabled and blind Supplemental Security Income recipients to return to work.

We have evaluated the recommendations made by the Disability Advisory Council (DAC) last year. Some of these have already been implemented. We are currently studying the feasibility of implementing many of the remaining recommendations. Some of those which should directly improve our ability to rehabilitate our beneficiaries and recipients include:

- Collecting data on the characteristics of beneficiaries that State vocational rehabilitation agencies (VRAs) accept, serve, and rehabilitate and the characteristics of those not served by State VRAs and why.

- Working with the Rehabilitation Services Administration to use compatible automated data systems to collect and exchange data.

- Referring those beneficiaries who are likely to return to work as a result of vocational rehabilitation (VR) services.

- Encouraging State VRAs to involve employers and unions in the design and structure of job skills training programs for SSA clients involved in the rehabilitation process.

- Purchasing VR services di ctly from private sector VR facilities, Federal agencies, and State agencies other than the VRAs.

- Gearing VR services for SSA beneficiaries more towards job placement and sustained gainful employment.

A major part of our initiative and the primary means by which we are testing many of the DAC recommendations is the Research Demonstration Project (RDP). The RDP is the most extensive research

program in SSA's history. We are currently funding approximately 80 research projects that are testing a wide range of techniques for stimulating and coordinating effective approaches for returning disabled individuals to work. These projects involve working with disabled applicants and beneficiaries, public and private sector providers of rehabilitation and employment services, private employers, trade unions, physicians, and others involved in rehabilitating disabled individuals.

In addition, we have a number of Agency-initiated activities underway which supplement the DAC recommendations and RDP projects and are designed to accelerate client reentry into the workforce. These include:

- o SSA regional office projects designed to establish an interactive relationship between private sector employers, public and private interest groups and others.

- o Improvements to the program by which we reimburse the State VRAs for rehabilitating SSA's beneficiaries and recipients. These activities include streamlining and automating many of our processes as well as revising our policies and procedures relating to reimbursement of the VRAs.

- o A number of activities to increase public awareness of SSA's work incentives to ensure that people understand how such incentives can help them return to work and that they take advantage of such incentives. These include publication of informational materials, revision of our letters and notices, and training of SSA's employees who deal with the public.

I am confident that the changes in the VR program that we have implemented, as well as the activities and projects that we have underway, will enable SSA to increase the number of beneficiaries and recipients that are rehabilitated, return to work and remain off the disability rolls, thereby saving us money.

Personal Earnings and Benefit Statement Project

Question. Last year you began the personal earnings and benefit statement initiative (PEBS) to provide enhanced earnings and benefit statements to workers. During the initial phase of the project, you sent the newly enhanced statements to persons requesting information on their earnings history. I understand you have plans to routinely send these statements to most covered workers on a periodic basis.

Can you describe the current status of the PEBS project in terms of its overall direction, and target dates for implementation?

Answer. In August 1988 we began issuing the new Personal Earnings and Benefit Estimate Statement (PEBES) to workers on request. PEBES, which replaces the prior earnings statements, contains detailed information earnings information and comprehensive benefit estimates which will help people do their own financial

planning. As SSA moves toward its vision of the future, we will continue to develop ways of informing and educating the public. We will continue to evaluate PEBES to determine the most effective and efficient means of providing this information to the public.

Question. How has the public reacted to this new service?

Answer. We have had a very positive public response to this new service. Already we have processed over 3.9 million requests for earnings statements.

Cost of PEBES Project

Question. What has been the cost of the PEBES project in terms of:

a. Development costs (software, hardware, etc.);

b. Operating costs in FY 1988 and projected costs in 1989, and

c. The anticipated costs when fully designed?

Answer. Development and validation of the Personal Earnings and Benefit Estimate Statement (PEBES) system began in fiscal year (FY) 1987 and concluded in FY 1988. It required a total of about 6 workyears of, primarily, computer programmer and requirements analyst time in SSA's Office of Systems Support. We estimate the cost of the 6 workyears, including salary and benefits, at about $260,000.

In FY 1988 SSA processed 3.9 million earnings statement requests at a cost of about $7 million, including salaries and printing and postage costs. This represents the annual cost for responding to requests from the public for earnings statement information, and it includes the new Personal Earnings and Benefit Estimate Statement which was announced on August 4, 1988.

The new PEBES replaces the prior earnings statements and is a considerable improvement over the old ones which provided only limited earnings information. PEBES contains more detailed earnings information and provides comprehensive benefit estimates which will help people do their own financial planning.

Because of the improved earnings and benefit information now available, the volume of requests for earnings statements has increased. In the President's FY 1990 budget request, SSA estimated annual costs of about $13 million in FY 1989, including salaries, printing and postage, to process 6 million earnings statement requests.

Wage Reporting Discrepancies

Question. Employers sometimes provide SSA information that only partially resolves reporting differences the Social Security Administration is trying to reconcile or that had tax implications for IRS. The same occurrence could be true for cases having tax

revenue potential that are initially worked by IRS. Employers may respond to IRS with information to suggest that they did not report to the Social Security Administration all wages on which they paid taxes. At what dollar threshold does the Social Security Administration believe it should reasonably consider employer reporting differences reconciled?

Answer. We believe the current tolerance established in the Memorandum of Understanding between the Social Security Administration (SSA) and the Internal Revenue Service (IRS) is reasonable. SSA will attempt to resolve all earnings differences that could give a person at least one more quarter of coverage. Any employer reporting an amount which results in a difference of less than a quarter of coverage will not be reconciled. A quarter of coverage is the minimum amount needed to receive one work credit under Social Security. A maximum of forty work credits are needed to be insured for Social Security retirement benefits. The amount needed to earn one quarter of coverage in 1989 is $500.

Question. Do IRS and the Social Security Administration exchange information arising from their reconciliation efforts that indicates all taxes on wages may not have been paid or that all wages may not have been credited to workers?

Answer. Yes, SSA and IRS share wage reporting data. The SSA-processed employer W-2 FICA wage reports are compared with FICA wage returns on which employers have reported taxes due the Internal Revenue Service. From this SSA learns which employers may not have reported to SSA all wages earned by their employees. SSA contacts those employers that reported to IRS greater wage amounts than reflected in their wage reports to SSA.

Likewise, if employers report to SSA greater wages paid than are indicated on their wage reports to IRS, IRS contacts the employer for additional taxes.

Suspense File

Question. The Social Security Administration maintains a suspense record system that contains wage records which because of errors prevents the crediting of earnings to a proper account.

How many individual wage items and how much in wages has been recorded in the suspense file from its inception through tax year 1987?

Answer. For the period from tax year 1937 through tax year 1987, 175,930,519 wage items, representing $133,352,178,788.19 in wages, are unidentified and recorded in the suspense file. To put those numbers in their proper perspective, that represents 1.6 per cent of all wage items and 0.6 per cent of wages.

Question. How many wage items and in what amount were recorded in the suspense file in the last year?

Answer. For tax year 1987, 6,024,267 wage items worth $18,705,870,935.68 were posted to the suspense file.

Question. What steps has the Social Security Administration taken to resolve questioned wage items before they are posted to the suspense file?

Answer. The Social Security Administration makes every reasonable effort to identify invalid wage items before they are posted to the suspense file. These efforts consist of two steps:

1. Correcting initial data entry errors.

2. Electronically manipulating items to identify number transpositions and minor name errors.

Question. What subsequent actions are taken to post items out of the suspense file?

Answer. Additional actions which help to identify and reinstate items from the suspense file include:

1. Correspondence requesting correct name and number information is sent to wage earners where possible, or to the reporting employers.

2. Matches are attempted for items with addresses to the address data on the Internal Revenue Service's individual master file.

3. The screening of current reinstatements against the entire suspense file to ensure that there is never an item remaining in suspense if there is a matching reinstated item.

4. Every second year the unidentified items in the suspense file are reprocessed through the initial validation programs to take advantage of new name information which may have been received from wage earners and to test older suspense items with newly developed reinstating rules.

5. Personal contacts are made with large employers who report large numbers of, or high dollar value, unidentified items to request special assistance in identifying and reinstating those items. These special efforts generally involve the employers rescreening all their unidentified items against both payroll and personnel records to find better, newer or more complete identifying information.

6. Electronic selections of possible matching records are reviewed to determine if the selections meet identification criteria considering the use of nicknames, grossly misspelled names, Americanized foreign names, etc.

7. Each allegation by wage earners of earnings missing from their records is investigated. In many cases, using the information provided by the wage earner, we are able to locate the missing earnings in the suspense file and to reinstate the wages to the wage earners records.

SSA Could Do More in Sharing Welfare Applicant Information

Question. Almost all State welfare agencies require that the Social Security Administration verify welfare applicant's Social Security number. By insuring that welfare applicants have accurate Social Security numbers should result in fewer false referrals when matching against wage and unemployment compensation data. Indications are that the Social Security Administration only notifies the State making the Social Security number inquiry. SSA does not notify the requesting-State about all other surrounding States that may have also recently asked for verification of the same Social Security number.

I'm pleased to hear that the Social Security Administration has taken a more active role in helping States verify welfare applicant's Social Security number. I understand that Social Security has the capability to determine if surrounding States have also asked for verification of the same Social Security number in the recent past.

Does Social Security share with all States or at least surrounding States, queries related to Social Security number verification?

Answer. No, SSA does not share social security number (SSN) queries made by one State with other States. However, the General Accounting Office (GAO) is currently conducting a study involving SSN verifications received for welfare beneficiaries in the District of Columbia, Maryland and Pennsylvania. The purpose of the study is to determine:

1. If an applicant for an SSN in one State is already receiving welfare payments in another State; and

2. If there is a death record matching the SSN the applicant has provided.

GAO is expected to decide in about a month whether to extend the study or end it.

Question. Are there any particular legal or administrative problems that would preclude Social Security from sharing this kind of data with multiple States?

Answer. There are at least two possible legal impediments to sharing SSN verification data with multiple States:

1. In order to implement such a system, SSA would be required to create a new file derived from State inquiries and SSA responses. Although the file could be of value to the States involved, it would serve no program purpose for SSA. If SSA has no administrative need to collect and maintain this information, it would appear that under the Privacy Act SSA would have no legal basis for establishing such a System of Records.

2. SSN verifications for State-administered federally funded programs which require valid SSNs as a factor of entitlement are "matching programs" subject to the provisions of the Computer Matching and Privacy Protection Act of 1988 (P.L. 100-503). Section (O)(1)(H) of 5 U.S.C. 552a as amended by that law would seem to preclude sharing match information with anyone other than the specific parties to the matching agreement; i.e., a particular State and SSA.

Payroll Tax Deposits

Question. The Inspector General has estimated the Federal deficit can be reduced $7.76 billion the first year, $12.6 billion over 5 years, just by speeding up employer deposits of payroll taxes. According to the Inspector General, this savings could be achieved through administrative action, by requiring large employers to deposit withheld payroll taxes one day after the payroll disbursement date. The proposal would generate $4.6 billion in interest savings alone, over a 5-year period.

Have you discussed the feasibility of this proposal with the Secretary of Treasury?

Answer. The Inspector General's recommendation asks the Social Security Administration (SSA) to endorse one of a number of possible acceleration alternatives that can be proposed. A copy of the report was provided to the Treasury Department, and in its comments, Treasury states that while this proposal does not establish any new tax obligations, this enforcement proposal could be considered to involve tax increases by those affected. Any such increase would be contrary to the stated position of the President against new taxes. SSA defers to the Treasury Departments' position.

Question. The Inspector General claims the current system represents a windfall for large employers, allowing them to profit from the investment of funds by delaying deposits.

Why should employers be allowed to profit from investment of funds deducted from employee wages, while the Federal Government loses investment income?

Answer. As the Inspector General highlighted in a recent advisory report, current Treasury regulations allow employers to delay depositing withheld payroll taxes by as much as 11 days after the disbursement of wages.

Having use of the tax deposits at an earlier date would enhance revenues and be a positive change for the trust funds. Reduced turnaround between collection and deposit of taxes would provide immediate fund access for investment purposes.

It is the responsibility of the Treasury Department to collect Federal Insurance Contribution Act taxes. Since we do not know all the ramifications of a change to the deposit schedule, we believe Treasury is in a better position to assess the advantages and disadvantages of another change to the deposit schedule.

Supplemental Security Income (SSI) Board and Care Homes

Question. Since the mid-1970's numerous charges of poor care and abuse have been leveled at board and care homes. The Federal Government's efforts to regulate board and care homes have been hampered by lack of direct Federal funding of these facilities.

What is the most recent estimate of the number of such facilities?

Answer. The February 1989 GAO report "Board and Care" states the following: "A 1987 industry survey of state licensing board agencies identified about 41,000 licensed board and care homes with about 563,000 beds serving the elderly, mentally ill and mentally retarded. However, the agency qualified its estimates as incomplete due to the wide variety of board and care definitions and the fact that some states were just beginning to license board and care homes." SSA knows of no more recent information.

Question. How many SSI recipients reside in board and care homes?

Answer. We do not have information about how many SSI recipients reside in board and care homes.

Question. How many board and care homes are the representative payees of SSI recipients?

Answer. Information from August 1988 indicates that 166,399 SSI recipients had representative payees which were institutions, including hospitals, nursing homes, board and care homes, etc. Those recipients whose payees are board and care homes would be a subset of this number; we do not know how many there are.

Question. Other than the Keys Amendment (sec. 1616(e) of the Social Security Act), which allows States to reduce the SSI checks of residents of homes not in compliance with State regulations, what methods to regulate board and care homes are being considered?

Answer. The responsibility for regulating board and care homes rests primarily with the States. The Department of Health and Human Services proposes to conduct an assessment of health and safety conditions and quality of care in board and care homes in a variety of regulatory climates. If this study is able to document a relationship between specific regulatory practices and living conditions of board and care residents, the Department will be better able to help States carry out their oversight functions.

Question. Are charges of poor care and abuse still being leveled against board and care homes?

Answer. It is true that there continue to be reports of instances in which board and care residents have been exposed to hazardous conditions or worse, or have received inappropriate care.

Technical and Management Improvements

Question. You have reduced the scope of computer modernization. Could you describe the difference between the original plan and the current plan, the project cost and completion date for modernization, and the status of the various software modernization projects?

Answer. In 1982 SSA established the Systems Modernization Plan (SMP), a 5-year plan to meet the crisis SSA faced at that time in its outdated and inadequate automated data processing (ADP) systems. The SMP addressed a broad range of ADP problems, including data bases, applications software, data communications networks, computing capacity, and the management of a state-of-the-art ADP facility. The original plan was estimated to cost $478.5 million, including ADP and telecommunications equipment and contractual services, as well as costs for personnel, training, supplies and travel associated with executing the SMP.

The SMP was not intended to be a static plan; activities in the original plan were modified as technology changed and as changes in priorities occurred. The SMP has been successful in modernizing SSA's outdated ADP equipment and software, catching SSA up to its expanding workloads, and contributing to major improvements in every facet of service delivery. The current estimate of total SMP expenditures, fiscal years 1982 through 1988, is $460 million.

Three of the original four SMP goals have been met (for the Data Base Integration Program, the Data Communications Utility Program, and the Capacity Upgrade Program), as well as the added goal of the Systems Operations Management Program. (It should be noted that although the capacity increases achieved have fulfilled the original SMP objectives and allowed SSA to meet critical needs through 1988, additional capacity is now needed to run new software which has already been developed for ongoing operations and future projects.) The fourth of the original SMP programs, Software Engineering, has achieved many of its original goals of developing a modernized benefit payment system for the Social Security programs. Additional improvements are scheduled to be completed in 1990.

SSA has made significant achievements in software modernization, including:

- Over 4,000 programmatic systems were documented, enhancing problem resolution and promoting greater responsiveness to legislative change.

- Over 4,000 programs were converted to structured format, simplifying maintenance and greatly extending their lives.

- The Cost-Of-Living Adjustments process was improved, reducing the time it took from 3 weeks around-the-clock processing to 25 hours.

- SSA automated the generation of 2,500 Supplemental Security Income notices per day.

- o SSA developed a new Software Engineering Technology manual which provides standards and guidelines for system developers.

- o The most significant software achievement, both in terms of service to the public and efficiencies to SSA, is the collection of modernized systems called Program Benefits. The Modernized Claims System (MCS), now in use nationwide, is the first component of Program Benefits. Additional software releases will provide incremental functional capability; and when Release 3.3 of the MCS is completed in 1990, SSA will have completed all of the original objectives of the SMP.

SSA's experience in implementing the SMP and evaluating its results led to a refocusing of modernization activities and development of the Agency Strategic Plan, which now guides SSA's current systems strategy and provides overall direction to systems planning. The Strategic Plan provides a comprehensive, service delivery-oriented vision for the future, and the remaining SMP initiatives are subsumed in the broader context of the Strategic Plan. Modernization and continued improvement in service delivery are ongoing tasks of the Agency under the Strategic Plan, rather than short-term projects with specific ending dates.

Question. What difficulties led you to reduce the scope of the plan?

Answer. Rather than a reduction in the scope of modernization, the refocusing strategy began as SSA's attempt to ensure that its systems resources were expended in those areas most critical to its service mission. After 5 years of working to implement the SMP, SSA recognized that there was excessive emphasis on hardware, that software development was slow, and that the Agency carried over large balances in its ADP/telecommunications funds from year to year.

Refocusing became SSA's implement to sharpen its modernization goals and revise them to focus on using automated systems to improve service rather than simply to modernize automated systems. As a result, SSA's software development process is more disciplined, and accelerated progress is being made that has direct impact on service to the public. The results have been better overall direction for the modernization, renewed emphasis on customer service, increased focus on software, and improved management.

Question. In a March 1987 report, GAO detailed over 50 recommendations to improve management and operations.

What are you doing to ensure that your actions to correct the problems identified by GAO are accomplishing their intended effects?

Answer. In response to the initial March 1987 management report, we moved quickly to delineate the 50 major recommendations, assign lead component responsibility for implementation planning, and establish an implementation tracking system within my office to ensure timely action. Corrective action on all of GAO's recommendations is either completed or has resulted in ongoing

activity. In addition we have integrated some of GAO's suggestions into our Agency planning processes, including our strategic planning. The results of these actions are summarized in a recent report of a follow up review by GAO. Their draft report says "The Commissioner and her staff have exhibited much needed leadership in establishing agency-wide goals and objectives and developing tracking systems to assure accountability."

Automation Strategy

Question. We understand your Office Automation Strategy proposes to provide the Agency with 35,630 workstations by 1991. The estimated cost of the required investment which covers minicomputers, mainframes, and related software is $251.2 million over 5 years.

Could you provide the specifics of this procurement in relation to existing procurement commitments under the Microcomputer for Operations and Terminal Acquisition projects?

Answer. In March, 1988, SSA had a total of 27,550 workstations in place or under procurement commitment. This total consisted of 22,000 Terminal Acquisition Project (TAP) terminals, a Microcomputers for Operations (MOP) procurement of 4,550 workstations and 1,000 workstations previously purchased. An additional procurement of 8,080 microcomputers is scheduled and would bring the total in FY 1991 to the 35,360 workstations referred to in the question. However, an additional 4,500 TAP terminals are also being acquired under optional quantity buys that would bring the workstation total to about 40,000 in FY 1991.

The Terminal Acquisition Project (TAP) terminals are not part of the Office Automation project. These terminals are used for programmatic purposes to update and access the information available on SSA's main systems (e.g., the modernized claims system).

Office Automation workstations are personal computers that are used for various administrative functions such as writing a variety of correspondence to claimants and others, maintaining local office files and data, and doing various automated computations. These applications will be expanded under the Office Automation initiative.

In addition to the purchase of workstations, much of the Office Automation resources will be used to institute various connectivity and office automation functions including electronic mail, local area networks (LAN), wide area networks (WAN), training and ongoing maintenance. Although the long-range strategy for Office Automation could cost as much as $251.2 million, completion of the program and total costs will depend on resources made available through annual appropriations for SSA's Information Technology Systems budget.

Wage Reconciliation

Question. On July 12, 1988, the Social Security Administration and the Internal Revenue Service agreed to undertake specific actions to improve the Combined Annual Wage Reporting system. A joint study by both agencies found that poor linkage between their records

contributed to their having different wages on record for the same employers.

What is the status of actions to reduce the occurrence of apparent reporting differences caused by employers' use of multiple employer identification numbers?

Answer. Since employers' use of multiple employer identification numbers (EIN) has contributed to differences in the wage records of the IRS and SSA, IRS has agreed to provide SSA with more current data on employer changes to EINs as they occur. This should result in fewer unmatched cases, because we will be able to resolve or eliminate more of the cases involving different EINs. In addition, IRS is changing reporting forms and instructions to increase employer awareness of proper reporting requirements, which should help clear up this problem.

Question. What is the status of the proposal to encourage consistent wage reporting by revising form W-3 to require employers to show wage amounts reported on form 941?

Answer. The IRS has recently notified SSA that it is revising the Form W-3 for tax year 1990 to require employers to show wage amounts reported on the Form 941. Lead time is needed before this change can be implemented effectively, in order to make modifications to the employment tax returns, enhance related instructions, and get input from various payroll organizations.

Keeping Offices Open

Question. When you started out developing a toll-free "800" telephone service, it was billed as an extra option for clients, to avoid visits to an office to conduct their Social Security business. Now there are those who fear you are moving toward 800 telephone service to eventually replace the need for a network of community-based local offices.

Do you still pledge to keep the existing level of local offices open, to serve any citizens who prefer to deal with their Social Security problems face-to-face?

Answer. Yes. We expect to retain approximately 1300 field offices to provide the public the option of face-to-face service.

Question. Although you've kept offices open, they are getting smaller. Isn't it just a matter of time before they get so small that you'll have to close them?

Answer: Offices will be consolidated only when it is no longer practical to remain open because of declining workloads. SSA will complete its planned staff reductions during fiscal year 1990. In addition, our systems modernization and teleservice initiatives make it possible for us to reassign workloads. If a community continues to need face-to-face service, we will provide it.

Computer Work for Private Sector

Question. You have told the Committee you are running out of computer capacity and need a bill language change in the next

supplemental to lift the existing ceiling on computer capacity. At the same time, you apparently agreed to disclose Social Security numbers of millions of individuals without their consent.

How do you justify spending computer time for private businesses, when you tell Congress you need more computer capacity to handle Social Security work?

Answer. SSA performs a large number of Social Security number (SSN) verifications for our own internal purposes and as mandated by the Privacy Act (for example, verifying SSNs for welfare-related purposes.) The small number of computer runs which we have used to "negatively verify" social security numbers and names for private financial and credit organizations has not had a significant impact on SSA's computer capacity. In addition, private companies for which we have provided this service have reimbursed us for the cost of our work.

Question. We understand you have suspended this operation, pending further review.

Why did you originally agree to verify Social Security numbers for private companies which may be in violation of the Privacy Act?

Answer. There has been some discussion as to whether the Freedom of Information Act permits or the Privacy Act prohibits negative verification of SSNs for private companies; the issue was not clear-cut. Late in 1988 when the practice of negative verification was brought to my attention, I imposed a moratorium on the practice, and asked the Policy Council and the Office of General Counsel to review this practice. After meeting with them and receiving their advice, I decided that the practice of performing negative SSN verifications for financial and credit organizations must be ended permanently. SSA no longer provides such verifications.

Wage Posting

Question. The subcommittee is concerned that SSA is fulfilling responsibility to accurately post earnings to individual Social Security records. GAO reported in 1987 that $58.5 billion in earnings was not posted to approximately 10 million Social Security records from 1978 to 1984. How much of the $58.5 billion has been subsequently posted to individual earnings records? What is the status of any remaining earnings that have not been posted to individual earnings records?

Answer. We have subsequently completed our correspondence with employers for the years 1978 through 1983 and as a result of this work we have posted and/or resolved $28.8 billion for 6.3 million of the 10 million individual wage records.

Additionally, for years 1978 through 1983, responses were received from employers which indicated that employee data no longer existed. The wages initially represented by those 418,000 employer reports totalled $8.7 billion.

Our work for tax year (TY) 1984 and subsequent years is continuing. For TY 1984, we have mailed correspondence to all 611,000 employers involved and as of late April 1989 we have received 250,000 replies. The responses are currently being processed so data for TY 1984 are not yet available.

The remaining unresolved wages of $21 billion represent employers from TYs 1978 through 1983 who did not respond or for which the correspondence was undeliverable and all employers for TY 1984 for which work is continuing. We expect the TY 1984 effort to resolve a significant portion of these employee wages. We also expect to resolve additional TYs 1978 through 1984 wages not yet posted as they are identified in the future by affected employers and/or employees.

Question. Please provide the Subcommittee a year-by-year accounting of how much earnings have not been posted to individual earnings records.

Answer. A yearly breakdown of the posted and/or resolved wage totals for 1978 - 1983 discussed in response to the previous question is not available as our records are kept by employer reports. The annual breakdown of discrepant employer reports is as follows:

Year	Employer Reports
1978	382,000
1979	460,000
1980	383,000
1981	336,000
1982	331,000
1983	343,000
Total	2,235,000

These records represent employers who have indicated to SSA that no employee records for the years in question exist, or employers who did not respond or for whom correspondence has been returned as undeliverable.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

VOCATIONAL REHABILITATION

Question: The Omnibus Budget Reconciliation Act of 1981 requires the Social Security Administration to reimburse State Vocational Rehabilitation agencies for costs incurred for successful rehabilitation of disabled beneficiaries. Recently, however, I received a letter from the Vocational Rehabilitation agency in my state indicating that the SSA was not fully reimbursing states for costs covered under the 1981 Act. What changes, if any, have been

made by the agency for determining the reimbursement of vocational rehabilitation claims from state agencies?

Answer: SSA has made several changes in the procedures for determining the reimbursement of vocational rehabilitation claims from state agencies. First, one of the four formula options available for State selection prior to October 1988 was found to overstate indirect costs significantly, so this option was replaced with a more accurate option.

In addition, SSA has updated the cost/benefit analysis procedure used in calculating expected savings to the trust fund and general revenues, to include factors of age, sex, work history and average time on the rolls to provide a "cap" for high cost claims. For example, if we have a reimbursement claim for $20,000 and the analysis determines only $10,000 in savings to general revenues, SSA will award only the $10,000.

The changes are effective only for claims in which VR services ended after September 30, 1988, so the full effect of the changes are not expected to be realized until FY 1991.

Question: What growth has there been in the cost of the VR program?

Answer: The following table summarizes the totals of paid claims ($ in millions).

Fiscal Year	$ Paid
1983	$ 0.2
1984	$ 4.2
1985	$ 6.5
1986	$20.5
1987	$27.7
1988	$26.2
1989(est)	$54.1

Question: What growth has there been in the volume of claims since the 1981 Act?

Answer: SSA began receiving claims under the 1981 Act in January 1983. The following table details the volumes of claims received in each fiscal year:

Fiscal Year	Claims Received
1983	3,626
1984	7,739
1985	5,448
1986	6,735
1987	8,137
1988	11,032

Question: What factors does the SSA believe have contributed to program cost and claim growth?

Answer: SSA believes that program cost and claim growth is evolving from these factors:

- o increases in average case costs, tied to:
  - increase in length of average rehabilitation service period eligible for reimbursement
  - 1986 Amendments requirement to consider, and provide where feasible, expensive rehabilitation engineering technology in each case before closure
  - advances in expensive medical technology needed for success in some rehabilitation cases
  - more successes now possible with this new technology, at greater cost for each, especially for blind cases
  - fatal injuries a decade ago are not always fatal today; Shock-Trauma centers have created a new population of very expensive rehabilitation cases
- o growing State activity as they recognize more and more the potential value of SSA's VR program to their funding levels:
  - one of the Commissioner's goals has been to encourage increased State activity in VR, to help remove more successful rehabilitants from benefit rolls
  - improvements in State outreach efforts
  - targeting SSI and DI beneficiaries more
- o heavy use by States of one optional formula which was found to significantly overstate indirect costs (this option was eliminated for all claims in which VR services ended after September 30, 1988)
- o use by SSA of an oversimplified cost/benefit analysis formula in determining savings to the trust fund or general revenues (this formula was replaced with a more accurate one, effective October 1, 1988, which considers additional factors of age, sex, work history and average time on the rolls)

Question: Has the SSA taken any action to control the cost of the program, either in claims volume or average cost of claims? If so, what?

Answer: Yes, SSA has taken action to control program costs in average costs per claim, but not in claims volume. We also are reviewing our VR policy to ensure that the program is cost beneficial to the trust funds and the general fund. Our goal is to get as many people as possible back into the productive workforce, benefiting the individuals and the Federal government.

One of the four formula options available for State selection prior to October 1988 was found to overstate indirect costs significantly, so this option was replaced with a more accurate option.

In addition, SSA has updated the cost/benefit analysis procedure used in calculating expected savings to the trust fund or general revenues, to include factors of age, sex, work history and average time on the rolls to provide a "cap" for high cost claims. For example, if we have a reimbursement claim for $20,000 and the

analysis determines only $10,000 in savings to general revenues, SSA will award only the $10,000.

The new formula option and the new cost/benefit analysis are effective for any claim in which VR services ended after September 30, 1988.

SSA discourages States from sending claims that clearly would not qualify for this reimbursement. Other than these kinds of general guidelines, we make no attempt to control growth of claims volume. It is assumed that an increase in the volume of reasonable claims would represent increased attempts to serve our beneficiaries, with an expected result of removing more of them from the rolls after successful rehabilitation.

SUBCOMMITTEE RECESS

SENATOR HARKIN. The subcommittee will stand in recess until Thursday, April 13 at 2:30 p.m.

[Whereupon, at 12:22 p.m., Wednesday, April 12, the subcommittee was recessed, to reconvene at 2:30 p.m., Thursday, April 13.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

THURSDAY, APRIL 13, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 2:35 p.m., in room SD-138, Senate Dirksen Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senator Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FAMILY SUPPORT ADMINISTRATION

STATEMENT OF CATHERINE BERTINI, ACTING ASSISTANT SECRETARY

ACCOMPANIED BY:

MICHAEL STURMAN, ASSOCIATE ADMINISTRATOR, OFFICE OF FINANCIAL MANAGEMENT

HOWARD ROLSTON, ASSOCIATE ADMINISTRATOR, OFFICE OF PROGRAM EVALUATION

JAN MUCKA, ACTING DIRECTOR OF LIHEAP, OFFICE OF COMMUNITY SERVICES

DENNIS WILLIAMS, DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. The subcommittee will come to order.

Today we will hear testimony from two agencies, the Family Support Administration and the Office of Human Development Services.

The Family Support Administration has responsibility for entitlement programs which exceed $11 billion including aid to families with dependent children and child support enforcement. They also administer discretionary programs which take big hits in the Reagan-Bush budget, Low-Income Home Energy Assistance Program, refugee and entrant assistance, the community services block grant. Combined cuts suggested by the President in these three programs exceed $800 million.

I am particulary concerned about the unnecessary funds that are being spent for welfare hotels, which are not only an unwholesome place for children but represent an expense which is three or four

times higher than the cost of permanent rental housing. I want to hear about the steps that are underway to resolve this wasteful spending.

The Office of Human Development Services fares better in the President's budget. Most programs for the elderly, children, and developmentally disabled are frozen at last year's levels while Head Start is slated for a $250 million increase. I want to explore with the Director of the Office of Management Services, Mr. Robert Stovenour, the issue of open-ended entitlement funding for foster care administrative costs which has experienced explosive growth in recent years.

At this point I would hold the record open for any opening statements by my ranking members, Senator Specter or any other Senators on the subcommittee.

PREPARED STATEMENT

We will begin with testimony from Catherine Bertini, who is Acting Assistant Secretary of Family Support Administration. Welcome to the subcommittee. Please identify the people who are with you, and if you could summarize your statement we would appreciate it.

[The statement follows:]

STATEMENT OF CATHERINE BERTINI

I am pleased to be here today to talk about the fiscal year 1990 Family Support Administration budget.

First, I would like to discuss the priorities within the Family Support Administration in President Bush's budget. These include maintaining support for the Aid to Families with Dependent Children (AFDC) and Child Support Enforcement (CSE) programs, and implementation of the welfare reform provisions included in the Family Support Act of 1988.

- Our request continues to protect those in need. Under the AFDC program, full funding will maintain benefits to more than 3.7 million families. At the same time, our investment of $1,033 million in the enforcement of child support will lead to collection of $6.4 billion from absent parents to help to support their children. This represents an increase over estimated 1989 collections of $931 million, or 17 percent. Of this $6.4 billion, almost $2 billion will be collected on behalf of AFDC families, increasing their self-sufficiency and helping to offset the cost of providing that assistance.

- Implementation of last year's Family Support Act will also be one of our highest and earliest priorities. In 1990, this will involve States' transition to the new education, employment and training program for welfare recipients, which includes reimbursement for child care costs and other work-related expenses, as well as extended

child care and Medicaid benefits when an individual leaves the AFDC rolls. By working to implement these provisions, the Act will encourage AFDC recipients, especially young single mothers, to develop skills they need to become self sufficient. We will place particular emphasis on the need for education as an ingredient for self-sufficiency.

A key element for effective implementation of this legislation is close working relationships with the Department of Labor and the Department of Education to coordinate our efforts. We will urge that the same coordination efforts take place at the State and local levels in order to prevent duplication and maximize the use of all available resources.

In addition, the Act strengthens several of the provisions in the Child Support Enforcement program, such as requiring States to use mandatory guidelines to set the level of child support awards and immediate wage withholding. Increasing child support collections is another very effective method for improving a family's likelihood of becoming self-sufficient.

o We also will be building on our aggressive and successful efforts to strengthen the child support enforcement process in the States through a variety of proven management and program strategies. These include: the completion of a national Child Support Enforcement Network (CSENET) to integrate

interstate regional networks for improved interstate collection activities; increased efforts to develop comprehensive child support ADP systems; improvement of coordination with AFDC agencies; and continued encouragement for States to aggressively use all of the child support techniques allowed by the law.

Funding for many activities of the Family Support Administration is contained in the residual freeze category, which includes numerous programs across the government. For all these programs, in aggregate, 1990 outlays would not exceed total outlays for such programs in 1989. This does not mean that each Federal program within this category must be frozen. The freeze is flexible in that it allows for negotiations between Congress and the Administration to determine appropriate funding priorities.

As budget negotiations between the Administration and the Congress move forward, we are treating the Reagan budget proposals as Bush Administration proposals. I would now like to outline for you some of the key features of those budget proposals.

The budget includes $1.1 billion for the Low Income Home Energy Assistance program (LIHEAP). Energy prices have stabilized in recent years following sharp fluctuations in the early 1980's, allowing home energy needs to be met in part by other sources of assistance, such as petroleum overcharge settlement funds. Furthermore, States continue to transfer LIHEAP funds to other block grants--28 States transferred $66 million in 1988.

For Refugee Resettlement and Entrant Assistance programs, the budget request is $242 million. This request

is based on, and was consistent with, Department of State estimates that 84,000 refugees will be admitted during FY 1990. In recent weeks, the State Department has requested funds for an additional 28,500 refugees to be admitted in FY 1989. HHS is presently exploring ways to fund the resettlement costs for these additional refugee entrants. The original level of funding will fully subsidize the States' share of assistance costs for 15 months to categorical refugees and for 12 months to non-categorical refugees.

For State Legalization Impact Assistance Grants (SLIAG) in FY 1990 -- the third year of this four year program - $444 million is requested. This represents a $300 million reduction from the amount that would be available under provisions of the Immigration Reform and Control Act of 1986 (IRCA). This proposal is based on information from State applications which indicates that the almost $1.6 billion which States will receive in 1988 and 1989 will be more than sufficient to assist States to meet the major costs they incur which result from the passage of the Immigration Reform and Control Act of 1986.

A complete phase-out of the Community Services Block Grant also is proposed in FY 1990. Given budget constraints and the need for Federal budget deficit control, we believe that States should assume a greater share of the financial responsibility for provision of services previously funded under this grant program.

The FY 1990 budget also includes a first-time request of $350 million for a new appropriation: Payments to States for AFDC Work Programs. These funds will provide transitional funding for States which maintain their Work Incentive (WIN) programs during part or all of FY 1990. In

addition, this appropriation will fund States which begin the new Job Opportunities and Basic Skills Training (JOBS) program created by the Family Support Act of 1988. States can begin to establish JOBS programs in July 1989; all States must have such programs by October 1, 1990.

Finally, a total of $78.1 million is requested to administer Family Support Administration programs in FY 1990. This request will support 1,029 full-time equivalent employees (FTE's). Included in this request is an estimated $1.6 million in user fees which would be collected from States using the new, expanded Child Support Enforcement Network in its first year of operation.

In closing, let me say that the budget request just presented to you reflects our sincere commitment to help poor women, men and children by encouraging self sufficiency and independence and our determination to support and sustain American families by aggressively seeking to enforce the absent parent's responsibility for their children's economic well-being. We must all work together to achieve those goals. At the same time, we cannot forget our obligation to assist in every way we can in the attempt to help reduce the Federal deficit which ultimately results in less resources being available to meet our society's many pressing needs. Therefore, we must strike a balance between prudently managing our scarce resources to meet the needs of the poor and identifying opportunities for reduced Federal spending when needs and priorities change.

INTRODUCTION OF ASSOCIATES

Ms. BERTINI. Thank you, Mr. Chairman. I would like to introduce from my left to right the people who are with me: Jan Mucka, who is the Acting Director of the Low-Income Home Energy Assistance Program [LIHEAP] in the Office of Community Services; Michael Sturman, who is Associate Administrator for Financial Management in the Family Support Administration; Howard Rolston, who is Associate Administrator for the Office of Program Evaluation in the Family Support Administration; and Dennis Williams, who is the Deputy Assistant Secretary for Budget in the Department of Health and Human Services.

We also, Mr. Chairman, have several members of our staff here who are experts in other areas who may be called upon to provide answers to questions.

Senator HARKIN. Fine. Please proceed with your summary.

Ms. BERTINI. I am pleased to be here today to talk about the Family Support Administration's budget for fiscal year 1990. First, I would like to briefly summarize in three parts the priorities as related to the Family Support Administration in President Bush's budget.

First of all, we have made implementation of last year's Family Support Act as our most critical objective. Beginning in July 1989 and continuing during fiscal year 1990, this will involve States' transition to new education, employment, and training programs for welfare recipients, programs which include reimbursement for child care costs and other work-related expenses as well as extended child care and Medicaid benefits when a family leaves the AFDC roles.

Through implementing these provisions, particularly the JOBS program, job opportunities and basic skills training program, the act will encourage AFDC recipients, especially young single mothers, to develop skills they need to become self-sufficient. Together we must do all we can to encourage welfare recipients to become productive members of this country's work force.

Mr. Chairman, I want to leave my prepared remarks for a moment to tell you that we are very pleased to report to you that today, on the statutory deadline, April 13, we have delivered to the Federal Register our JOBS regulations to implement the Family Support Act JOBS program. We view this as part of the administration's commitment to this program and to the building of self-efficiency among people throughout the country.

Second, we continue to emphasize protection of those most in need. Under the AFDC programs, full funding will continue to maintain benefits to more than 3.7 million families. At the same time, our investment of over $1 billion toward enforcement of child support obligations will lead to collection of $6.4 billion from absent parents to help support their children. This represents a significant increase over estimated 1989 collections and in particular should be of benefit to AFDC families by increasing their self-sufficiency as well as easing the burden to Federal and State governments and meeting the cost of providing assistance.

Finally, we fully support President Bush's strategy to reduce the Federal deficit. This is an extremely urgent problem threatening

our Nation's economic health, and all levels of government, Federal, State, and local, as well as the private sector must together share in the burden of alleviating the deficit problem.

For our part, FSA has proposed spending reductions in most of the discretionary programs under our jurisdiction because of the critical need of reducing the Federal deficit. We have proposed reductions in the Low-Income Home Energy Assistance Program and Refugee Resettlement Program, termination of funding for community services programs, and partial rescission of the permanent appropriation for State legalization impact assistance grants, actions made necessary because of the critical Federal deficit problem.

As you know, the President has proposed a flexible freeze, and the cuts I have mentioned above will be on the table during discussions and negotiations between Congress and the administration over specifics involving the flexible freeze.

While we would all agree that these programs are each individually important, they nonetheless do not constitute activities which require a unique Federal role. States have the flexibility and capacity to meet needs in these areas. The same cannot be said for other activities of concern to the Department; for instance, the national health crisis caused by the tragedy of AIDS and other disease-fighting programs of the National Institutes of Health. The HHS and FSA budget presentations reflect this priority.

In summary, the budget request we are defending today reflects our sincere commitment to help poor women, men, and children by implementation of the Family Support Act. We hope this will help encourage self-sufficiency and independence. We also will strive to continue our determination to support and sustain American families by aggressively seeking to enforce the absent parent's responsibility for his or her children's economic well being.

Finally, while we must all work together to achieve these goals, we also accept our obligation to share the burden in the effort to help bring the Federal deficit under control by making cuts in some areas. Failure to do so will ultimately result in less resources being available to meet our society's many pressing needs.

I will be happy to entertain whatever questions you may have.

Senator HARKIN. Thank you very much for your concise summary. Let me just start with a couple of items here that I have become aware of. I knew about it before, but until I took over the chairmanship of this subcommittee I did not realize the extent to which it was happening.

In January 1989 the General Accounting Office released a study that showed the cost of welfare hotels is three to four times higher than the cost of permanent rental housing for public assistance recipients. In New York City it costs $2,000 to keep a family of four for 1 month in one of these hotels, and I would just direct your attention to those charts over there.

The bright orange bars represent the cost of the hotels. The darker red shorter lines represent the actual housing, permanent housing, in New York City, as I said, $2,000 for 1 month; in nearby Westchester County, $2,300 a month. We also have it there for Essex County, NJ. We have Washington, DC. You can see it is almost two to one here in Washington, DC.

Despite the high cost, welfare hotels are typically located in filthy, dangerous areas amidst centers of drug trafficking and prostitution. Social workers have compared the hollow dazed expression of children living in these hotels to photographs from war zones.

It is not widely known that the Federal Government pays one-half the cost of these absurdly expensive hotel rooms through the AFDC emergency assistance appropriations. I see this as a gross abuse of this program. AFDC was not set up for this purpose. From everything I understand about AFDC, it should not be used for this kind of purpose. We have been unable, however, to find out exactly how much AFDC money is going into welfare hotels.

Does the Family Support Adminstration know how much of AFDC money is being spent on welfare hotels?

Ms. BERTINI. We pay for these AFDC programs in a couple of different ways: through emergency assistance and also through the AFDC benefit payments which include shelter payment costs, Senator.

Senator HARKIN. Say that again? Through AFDC payments?

Ms. BERTINI. And through emergency assistance.

Senator HARKIN. My question was how much are you spending.

Ms. BERTINI. We do not have specific information about that, sir.

Senator HARKIN. May I ask why?

Ms. BERTINI. Yes; I will ask Mr. Rolston to answer that.

Mr. ROLSTON. The States report to us their expenditures which are not broken out, for example, by shelter versus utility cost versus food cost or other costs, so that when they claim their expenditures either under emergency assistance or under the regular AFDC program, they report the grant in total. In some cases States have been able to supply rough estimates to us, but that is not normally reported to us, and we can certainly supply you for the record where States have supplied those estimates to us.

Senator HARKIN. I would like to know the estimates, but I see no reason why we cannot get an exact dollar amount. We are reimbursing the States; right? That is what it is. They put in a claim to reimburse the States. Why not say before we reimburse you, you have to lay out how much you are spending for these hotels?

Mr. ROLSTON. It would not be impossible to do that.

Senator HARKIN. Let me ask, is there a legislative prohibition against your doing that?

Mr. ROLSTON. There is not a legislative prohibition against expenditures being reported by category. They have not been reported by category in the past.

Senator HARKIN. Is there any reason that I am unaware of?

Mr. ROLSTON. There would be a substantial burden on States to break out expenditures that way. For example, there are many States that pay for shelter through a flat grant. They pay, say, $400 per month for a family of four. That might be reduced if the family has income. It would be difficult for States to allocate precisely what the payment to the individual was for in many cases, and it is not just a flat amount in which the parts are not separately identified.

So it would be a fairly substantial reporting burden on States to break out the payments made to individuals by what they are for.

Senator HARKIN. I have to believe they have those records. They know. They send the checks out.

Mr. ROLSTON. Again, they may just pay every family of four with no other income $428. They do not pay them $300 for shelter or $150 for food and so on. They pay them a flat amount frequently in numbers like this.

Senator HARKIN. Wait a minute. Back up. Maybe there is something I do not understand here. I asked my staff, and they told me these things go directly to these hotels. They do not go to the recipients.

Mr. STURMAN. If I could just trigger——

Senator HARKIN. Bring your microphone in.

Mr. STURMAN. If I could just mention some things. A lot of the abuses in these welfare hotels were pointed out by the Department. There is absolutely no disagreement with your views.

Let me give you some specific examples of what we have been trying to do within the Family Support Administration that I hope will trigger perhaps a different line of questioning.

For example, in Washington, DC, there were payments being made to the equivalent of the New York welfare hotels under an Emergency Assistance Program. We, in effect, told the District of Columbia we would no longer provide reimbursement for those payments because they could not document eligibility, they could not document rationale, they could not document how it fit within the State plan that they provided, and so we are not paying in the District of Columbia the payments for these kinds of abuses. The District still has not cleaned up its act.

In New York, as a consequence of the abuses in the welfare hotels, the extent of which was funded under the Emergency Assistance Program, the previous Administrator, Wayne Stanton, proposed regulations to tie emergency assistance funding precisely to the statutory language of the law. It was Congress which put a moratorium on our ability to publish regulations to limit the ability of cities like New York, like Washington, and some of the other ones in order to correct those abuses.

We do not know how much is being spent, but we know that the abuses occur, and we have been taking steps to correct those abuses. Absent congressional cooperation and our ability to enforce the law, we are going to continue to have those abuses.

Senator HARKIN. Tell me about this prohibition. When did that come into law? Can you tell me exactly where it is in the law? What is it a prohibition against?

Mr. ROLSTON. There are two ways that, for example, New York pays for welfare hotels. For people who are eligible for regular AFDC programs, they pay through an alternative shelter allowance. So if somebody is assigned to a welfare hotel, instead of paying whatever the family pays up to a certain maximum on family size they will assign that individual to a welfare hotel, and they will pay at a daily rate depending on the number of individuals.

One of the things that the regulation would do would be to prohibit alternative shelter allowances for individuals who are assigned to welfare hotels so that all individuals who had a certain family size would get a certain amount for shelter, and it would

prohibit these large payments for the individuals who the city assigns to welfare hotels. That is one mechanism that is in the regulation.

Senator HARKIN. Wait a minute. That is in the regulation?

Mr. ROLSTON. This is a proposed regulation on which Congress passed the moratorium prohibiting us from publishing the final regulation.

Senator HARKIN. When did Congress pass that moratorium? Last year?

Mr. ROLSTON. It was passed initially before that. It was extended in the McKinney Homeless Assistance Act of last year through I believe September 30.

Senator HARKIN. I was told by staff that it expires on September 30 of this year.

What is the other regulation?

Mr. ROLSTON. It is part of the same regulation. The other part of it is that New York and other localities also pay for individuals in welfare hotels through emergency assistance. In the statute it is pretty clear that you can pay emergency assistance to a family for 30 days in any 1-year period.

As the regulations were written in 1969, they were written slightly more expansively than what is in the law, and that was not too much of a problem for a long time.

At some point somebody caught on that if you read what was in our regulations very carefully, you might be able to pay for this for people, for example, who are in welfare hotels indefinitely.

That, as a matter of fact, is what has happened. I think the average family at one point in New York City was in a welfare hotel for about 13 months. So whereas the statutory language is quite clear that you are supposed to pay for no more than 30 days in a 1-year period, the regulation was a little broader, and there are a number of States that had people trying to figure out how they could pay for these costs and how they could get 50 percent matching.

What our proposed regulation would have done would be to go back to a strict reading of the statute where emergency assistance is for short-term help for one period of 30 days in a year. Again, that was part of the regulation that the moratorium was passed on.

Mr. STURMAN. Mr. Chairman, I think it is important to note that we in the Department cannot define what a State can do in terms of payment levels. All we can do is within the context of the entitlement provisions and we can write regulations about what the law says.

As Howard was explaining, in the Emergency Assistance Program our limits are to the extent to which it defines as 30 days. In the case of defining benefit levels under the AFDC Program, as long as the State follows its State plan, the State is the one who sets things like alternative shelter allowances or the basic shelter allowance itself. We have no control over what level a State sets for those.

Senator HARKIN. As I understand it, this is just an open-ended entitlement; right? It could be anything. I noted in the last 3 years it has doubled from $72 million in fiscal year 1987. The emergency assistance has gone from $72 million to $146 million in 3 years.

I guess, to make matters worse, GAO points out incidents of apparent fraud and excessive profiteering. One hotel reportedly made a net annual profit of $3 million, a return of 50 percent. Another scheme as reported by GAO in its January 1989 report, almost 17 percent of New York City issued checks in September 1986 to families for emergency hotel shelter were cashed by the hotels even though the families were not registered at the hotels for the periods the checks covered. This cost an estimated $1.4 million to pay for empty hotel rooms.

Have you looked at this GAO report of January 1989? You are aware of it; right?

Mr. STURMAN. We cannot quarrel with that. We just have no legal authority to do much about it.

Ms. BERTINI. Senator, there are several things we are doing because we share your concern about the excesses. That is definitely an understatement, in fact, on my part.

One of the things is, as you know, in the McKinney Act there is a demonstration project to look into how funds can be better used for housing, and we support full funding of that program.

Second, we have been asked by Congress to give a report by the end of June about how emergency assistance funds could be better used to help the homeless, and we are currently doing some research on that to offer some comments and proposals to you in that report. That is due to you by July 1.

As my colleagues have mentioned, of course, we promulgated the regulations on putting some limits on the use of emergency assistance as well.

Senator HARKIN. You will have that report here by July 1?

Ms. BERTINI. Yes.

Senator HARKIN. In that report you will spell out what you can do to fix this problem without necessarily throwing people out on the streets?

Ms. BERTINI. That is our intent, to suggest some alternatives.

Mr. ROLSTON. One thing I might mention, although we have no direct proof, it does appear that the threat of loss of funds to New York, at least if you believe what they say in the New York Times, has spurred the city to take action to develop some other alternatives, and the Federal pressure to withdraw the funds has apparently to some extent motivated them to look for other alternatives.

Clearly, though, if the moratorium is extended indefinitely, that would take the pressure off them.

Ms. BERTINI. There was also, Senator, some innovation going on in States. For the record, we would be glad to provide some information about a couple of programs, ways that they are trying to deal with the homeless problem without creating welfare hotels. I can think of New Jersey and California as two examples which we would provide you information about.

Senator HARKIN. Well, obviously I care about the homeless, and I also care about people who are poor and have families to take care of; but AFDC, to the best of my knowledge, was not set up to be a housing program.

Ms. BERTINI. That is correct.

Senator HARKIN. How many millions are we spending on this every year in housing assistance? How much is it, $146 million?

Mr. STURMAN. The $137 million, that is our estimate for 1990, is for all kinds of emergency assistance of which shelter emergencies are only a portion.

Mr. ROLSTON. Actually, in New York the great bulk of the amount of money that was spent for the individuals in welfare hotels was not out of the emergency assistance. It was out of the regular program.

Senator HARKIN. The regular AFDC Program?

Mr. ROLSTON. AFDC was the major way.

Senator HARKIN. Again, we do not even know how much we are spending on these. I still do not know why you cannot ask the States to break it out, because they have to know who they are sending their checks to.

Mr. ROLSTON. I believe we could make some pretty good estimates because I do think we know what it is per family, and we do have some estimates from New York in terms of the families, and we could provide that.

Senator HARKIN. Please give us those. Again, if this is a housing program, then it ought to come through housing. It should not come through AFDC.

Ms. BERTINI. Senator, there is a person in the audience who represents the American Public Welfare Association. If you wanted to get some response from States, if he were prepared he might tell you if that would be a difficult burden.

Senator HARKIN. Excuse me? I am sorry.

Ms. BERTINI. There is a member of the audience whom I know is from the American Public Welfare Association. They represent States, and they represent social service administrators, and he might be able to shed some light on whether or not this would be a possibility if he is prepared.

Senator HARKIN. I am told they are going to testify as public witnesses in May, so they can respond at that time.

Again, I have no quarrel that people who are low income need housing. Some of them need emergency housing, an immediate type of housing. But my two points are it seems there are no checks on the system. It is an open-ended entitlement. What does the State care? So it costs them $2,000. So what? Put them in it because you are going to reimburse 50 percent of it right away.

Ms. BERTINI. They have to come up with the other 50 percent, and as you know some States have budget surpluses, but States like New York have a significant problem with that right now, and so I would not like to suggest that the States easily spend that money. I think they spend that money specifically for purposes that they think are important. We do match it. That is right.

Senator HARKIN. It would seem to me that we should not be spending any more than—I mean if it was just slightly more than the normal cost of housing, you could understand that for an emergency basis, temporary, but not two, three, or four times as much, especially from what the GAO has told us about what these hotels are like. We know that.

It just does not make sense to me, and it just seems like there has got to be a better way of doing it and a better way of funding it with more checks on the system.

Again, I want to know if there is anything that we need to do here. You mentioned the moratorium. That ends in September. You have your report coming up here by July 1. That gives us some time to look at it.

It just seems to me we have a tremendous expense, and we really do not have a handle on it. Again, I do not want to see them kicked out into the street, but I do not want to see them winding up in these welfare hotels, either.

Ms. BERTINI. We share your concern, sir, and want to assure you that we are actively reviewing this and will be providing information and hopefully some constructive ideas to you in June.

Senator HARKIN. I look forward to that.

Let me move on to community services block grants. Once again you are proposing to zero out community services block grants which support a nationwide network of 900 agencies serving some of the most impoverished members of our society. Local community action agencies have been actively involved in efforts to combat alcohol, drug abuse, and assist the homeless. In many States these agencies administer the Head Start Program as well as LIHEAP and other things.

If we abolish the community action agencies, would we not simply have to create replacement agencies to run the programs such as Head Start and LIHEAP and other programs like that? Who would administer some of those programs?

Ms. BERTINI. We believe that the community services program is a program that is very close, as you mentioned, to communities, which is part of the name, and to individuals and organizations in those communities. It is one of those things I mentioned in my opening statement that we do not believe falls into the unique category of being something that needs to be administered and funded by the Federal Government but, rather, should be something that is community based and perhaps funded by State governments or by other communities. So that is one of the reasons why we have recommended not funding this program.

Also, again because we are dealing with a budget deficit and trying to make recommendations in order to help solve that deficit, this discretionary program was one that we thought we needed to make a change in in order to help serve that purpose.

Senator HARKIN. Is it true that the community action agencies leverage a significant amount of State and local funding to make use of volunteers?

Ms. BERTINI. Certainly the community action agencies use all sorts of different resources to fund their programs, not just Federal money.

Senator HARKIN. So the answer is yes, they use volunteers, they leverage the money?

Mr. STURMAN. The Head Start Program which originated in the community action environment is one of those that uses extensive use of volunteers which you will hear from our colleagues at HDS this afternoon.

Yes; our proposals are not a reflection that the community action agencies should be terminated. It is a matter of declining Federal resources and a need to deal with the budget deficit.

Senator HARKIN. Again, if we make the determination that we are going to assist these impoverished members of society and that we are going to continue a Head Start Program and we are going to continue the LIHEAP Program and we are going to continue these other programs, somehow they have to be administered, and if they are being administered by the community action agencies it takes $1 of Federal money to leverage the volunteers with local moneys, what are you going to get to replace it? Are you just saying do away with all those programs?

Mr. STURMAN. We are suggesting that in a budget priority setting, given the fixed amount of money that the administration had to work with in complying with the Gramm-Rudman targets for this year, there are some activities where only the Federal Government has the capacity to respond effectively. Using the examples of NIH, disease research, things like AIDS, the States and localities do not have a capacity to deal with those activities.

The Federal Government has a role in the Food and Drug Administration, Environmental Protection Agency, activities like low-income home energy assistance and the community services block grant and refugee assistance, which is a welfare program. In setting Federal budget priorities, you have to look at who can pick up where the Federal Government cannot.

Unfortunately, a lot of our activities are lumped in this agency, so we are going to get beat up in front of congressional committees; but nonetheless, the States do have the capacity to provide alternative funding. We are not saying that these are programs that should be terminated or phased out. We are saying that finances should be picked up in a different arena than the Federal Government.

Just to clarify a comment you made, the Low-Income Home Energy Assistance Program is not run entirely through the community action agencies. It is run by State welfare agencies as well, but there are a lot of activities that are funded——

Senator HARKIN. The Low-Income Home Energy Assistance Program?

Mr. ROLSTON. In some States it is run through the community action agencies.

Senator HARKIN. I am sorry. What did you say, Mr. Sturman? Let us get this corrected.

Mr. STURMAN. The funds often go through the State welfare agencies. I am told that about one-half the States use only community action agencies, but the other one-half run it strictly through the State welfare agencies or through a combination of welfare offices, community action agencies, and other local agencies.

Ms. BERTINI. Also, Senator, there are administrative costs in the LIHEAP Program as well for adminstration of LIHEAP.

Senator HARKIN. Again, I guess this is nothing new. I have been on this committee now for 4 years, and every year they have asked to zero out the community services block grants.

Mr. STURMAN. Just to keep the record straight, the Bush administration has said that all of these programs are in the residual freeze category. These are merely starting points for negotiation and if funding priorities shift, say, taking money from another account and putting it back into the community services block grant,

my interpretation is that that is not an issue over which the President will veto an appropriations bill because funds are restored into the community services block grant. It is a funding total that they are dealing with, and our budget represents what we believe to be funding priorities, but there are disagreements, and it is subject to negotiation.

Senator HARKIN. Last month I held a hearing with Secretary of Labor Elizabeth Dole, and I got her commitment to correct abuses which are wasting about $26 million a year in job training programs. Your agency is about to launch a new JOBS program. You mentioned that it is an entitlement program for welfare recipients, and it allows States to enter into the same kind of on-the-job training contracts where problems have been discovered in the Labor Department's Job Training Partnership Act.

It seems every time we have a change in administrations we have a new jobs program. I swear this is every 4 years. In fact, we may have even had two under the Reagan years. Now that I think about it, it seems like every change of administration there is some new jobs program to get the people off welfare and into jobs.

There was CETA, then JTPA, and now you have JOBS. I forget what came before Carter; manpower development training. This goes on and on. Every 4 years we get something new.

You want first year funding of $350 million for this program. This is one of your new programs; right?

Ms. BERTINI. Yes.

Senator HARKIN. I understand your welfare JOBS Program is expected to exceed $1 billion by fiscal year 1991. That is quite a growth. I guess my question is just one of procedure.

Will you work closely with the Labor Department to prevent duplication, overlap, in order to avoid some of the mistakes we made in the past on some of these programs? Do you have coordination? Are you setting up an immediate coordination?

Ms. BERTINI. Yes, sir; your question raises several points that I would like to address.

First of all, coordination is a key part of the JOBS Program. The JOBS Program, as you know, was part of the Family Support Act which is the result of a lot of discussion about welfare reform. President Reagan talked in his January 1986 State of the Union address about the importance of welfare reform in providing some meaningful help to welfare recipients, and that really put the issue back on the front burner, we think, in the public eye and certainly in Congress.

Many folks took the ball and ran with it, and there was a lot of discussion that resulted in Congress passing last fall the Family Support Act. The President signed it in October.

Some of the points in the act that are relevant to your question, sir, are, first of all, that in an effort to work toward self-sufficiency we provide welfare recipients, AFDC recipients, particularly those hardest to serve, mostly young single women with children, with an opportunity for better education, for job training and employment training and an opportunity to find jobs.

Also, the act required the State welfare agency to run this program to be administered but at the same time said that there would be a lot of coordination requirements starting with the De-

partments of Health and Human Services, Labor, Education, and Interior. We have taken that very seriously, and it has brought us to the table with the Departments of Labor and Education and Interior on many occasions.

I can report to you that we have developed a day-to-day active staff-to-staff relationship between the Departments of Labor and Education and HHS. We are trying to learn from both the mistakes and the opportunities, the pluses of programs like JTPA and other programs that Labor and Education have run in developing a strong operation for the Family Support Act or at least to develop regulations in which the States can develop strong operations in the Family Support Act.

Our Secretaries are also meeting about this because the JOBS piece of the Family Support Act is one of the top five objectives of Secretary Sullivan, and he and Secretary Dole and Secretary Cavazos are meeting to discuss these issues as well.

I might also tell you that we have also taken the congressional direction seriously in how we viewed this when we wrote the regulations to encourage States to have similar coordination activities. Some are required by the act, and some are encouraged.

We are also encouraging them to go to the local level as well so that the local communities, the local counties who will be running these JOBS programs will have something to say about bringing in and coordinating with not only Government agencies but education agencies, volunteer groups, businesses, and others in order to develop an effective program.

So we have very high on our list the coordination responsibilities, and in an effort to bring all different programs together so we do not have duplicative programs but rather use all the programs that currently exist most effectively and then use JOBS on top of that to create additional opportunities.

Senator HARKIN. Let us talk a little bit about LIHEAP. The National Consumer Law Center just released a report which disputes your contention that $700 million remains available for the Department of Energy, that $700 million remains available from the oil overcharge contract.

The report indicates only $130 million remains from the States, and 13 States have exhausted all of their money.

The report goes on to say only 20 percent of these oil overcharge funds are spent for low-income home energy assistance. That would seem to indicate only $26 million will be available from prior settlements to offset your $283 million proposed budget cut for fiscal year 1990.

What is your response to this analysis from the National Consumer Law Center?

Mr. STURMAN. I guess I am stuck with answering the question. We have not seen that report, but I can tell you that the figures that we have of some $670 million of undesignated oil overcharge funds are figures that came to us from the Department of Energy. Those figures are based upon State plans and reports which the individual States send into the Department of Energy.

The difference between the NCLC figures and the Department of Energy's figures, no matter who funded the contract, we believe is probably a definitional difference. What I mean by that is that the

figures that the National Consumer Law Center are reporting probably are not only the official figures that the States are sending to the Department of Energy under the plans or reports required in connection with the distribution of the oil overcharge funds but also other tentative plans that the State might have that have not yet officially been determined by the Governor or the State legislature or whatever bodies in that State deal with the distribution of those funds. That is probably the basic difference.

Which one is the better figure? I cannot tell you. We have official figures that the States report to the Energy Department, and NCLC is using a different definition.

In the long run, if you are asking my opinion, the States will probably eventually come down in their figures that NCLC is reporting to you, but that is the difference in the two numbers.

In response to your other figure, let me just mention that since 1986 approximately $3.2 billion in oil overcharge funds has been distributed to the States. Of that, about $400 million has been designated for low-income home energy assistance purposes.

I think the important point is that there is no formula specifying the percent or amount of oil overcharge funds which States must use under each permitted program. For example, States have broad flexibility to determine against which of the five categories the State designates those funds, four of them being the Department of Energy programs and the fifth LIHEAP.

I have figures here that show the States spending on LIHEAP as low as $20 or $30 million in 1 year in Exxon or stripper well funds, and last year it was maybe up around $160 million. The total is about $400 million.

Senator HARKIN. I have a letter here from the State of Iowa from the Governor's office saying that:

> Past reductions in LIHEAP have already had a serious effect. In 5 short years, LIHEAP has lost over $8 million in its program while serving the same number of households. The average assistance award has been reduced by over $120 per household during this period. We cannot absorb further cuts.

I have from $34 million in 1984 down to $25 million this year. Then it would go to $21 million next year. They say LIHEAP has been able to meet only 40 percent of the estimated need even with the couple of warm winters in a row we have had. So the need is out there.

Mr. STURMAN. I would not dispute those numbers. I would just remind the committee that the LIHEAP Program was enacted when OPEC was holding countries like the United States hostage against petroleum prices.

I have some figures here that I think might put that in perspective. LIHEAP was created as a supplement and not as a replacement for other kinds of financing. I just want to give you some figures on energy prices to show you and to place all of that into perspective at the time when LIHEAP was at its roughly maximum appropriation of nearly $2.1 billion in 1984.

One of the reasons why you can justify a decline in LIHEAP appropriations is because of the change in energy prices. People do not believe that not only have energy prices stabilized on average, but the three major categories of energy prices either have stabilized or have gone down between 1984 and 1988.

This is 1988 dollars compared to 1984 dollars. Natural gas prices have dropped 7 percent, fuel oil costs have declined 22 percent, and electricity costs have remained stable. That is just to indicate how you can place that in a slightly different perspective.

LIHEAP is a supplemental program. It is not an entitlement program. It is not a program to pay for everybody's energy prices.

Ms. BERTINI. Senator, the figures you mentioned from Iowa would make it on the low end of what is happening in some other States. In fact, our figures show that in fiscal year 1986 LIHEAP offset approximately 57 percent of the heating expenditures of low income households it served, and in 1987 that actually increased to 61 percent.

Senator HARKIN. Increased from when?

Ms. BERTINI. Between fiscal year 1986 and fiscal year 1987 there was an increase of 4 percent, from 57 to 61 percent of the heating expenditures that were offset. In other words, of the recipient low income households in fiscal year 1987, 61 percent of their heating costs were offset by LIHEAP.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I just had a couple more questions dealing with child support. I have to go vote right now, and so I will submit those, and if you would respond in writing.

Ms. BERTINI. We would be glad to.

Senator HARKIN. Thank you very much.

[A brief recess was taken.]

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

WELFARE HOTELS

Question. In January, 1989, the General Accounting Office released a study that showed the cost of "welfare hotels" is 3 to 4 times higher than the cost of permanent rental housing for public assistance recipients. In New York City it costs $2,000 to keep a family of four for one month in one of these hotels. In nearby Westchester County it's over $2,300 a month. This sure seems like a waste of the taxpayers' dollars to me.

Despite the high cost, welfare hotels are typically located in filthy, dangerous areas, amidst centers of drug trafficking and prostitution. Social workers have compared the hollow, dazed expression of children living in these hotels to photographs from war zones.

It is not widely known that the Federal government pays half the cost of these absurdly expensive hotel rooms, through the AFDC Emergency Assistance appropriation. I see this as an abuse of the program.

We have been unable to find out exactly how much AFDC money is going into welfare hotels. Does the Family Support Administration know how much AFDC money is being spent on welfare hotels?

Answer. We do not have fiscal data on State expenditures since there is currently no requirement that States report their AFDC expenditures broken down by shelter categories. However, we agree that the expenditures on welfare hotels cited in the GAO report are excessive and agree that homeless families should be offered a more supportive and responsive environment during their transition to permanent housing.

Question. The one thing we have been able to find out is that the Emergency Assistance appropriation, which is an open-ended entitlement and which funds welfare hotels, has more than doubled in the last three years (from $72 million spent in fiscal year 1987, to $146 million projected in the President's fiscal 1990 budget).

To make matters worse, GAO points out incidents of apparent fraud and excessive profiteering that cost the taxpayers millions. One hotel reportedly made a net annual profit of $3 million, a return of 50 percent. In another scheme, as reported by GAO in its January, 1989 report, "almost 17 percent of checks New York City issued in September 1986 to families for emergency hotel shelter were cashed by the hotels even though the families were not registered at the hotels for the periods the checks covered." This cost an estimated $1.4 million to pay for empty hotel rooms. Are you satisfied with the audits made by the Comptroller of New York City that estimated $1.4 million went to pay for empty rooms?

Answer. While we are not familiar with the sampling methodology employed by the New York City Comptroller and have

been unable to comment on the reliability of the estimate which indicates that $1.4 million went to pay for empty rooms, this Administration strongly supports efforts to curtail waste and abuse and cannot accept practices which permit payments to be made for empty rooms.

With regard to the New York City situation, information supplied by New York City officials states that the number of families housed in hotels fell from 3,154 in December 1987 to 2,728 in December 1988 largely because New York City plans to eliminate the use of hotels in two years, rather than five years as originally planned. By June 1990, New York City anticipates the number of families in hotels will fall to 1,918 and by June 1991, these hotels should be completely vacated. The Family Support Administration encourages and supports initiatives to eliminate the use of welfare hotels and to offer homeless families a more constructive environment during their transition to permanent housing. Such initiatives, however, should guarantee short term stays in transitional facilities. Our FSA Regional Office staff has been working with New York State officials to develop a more cost effective and socially responsive approach to homelessness.

Question. To your knowledge, were any of the hotel owners who cashed checks for empty rooms fined or otherwise prosecuted? Apparently, according to GAO, one out of the six checks from the City was cashed when there was no one staying in the room.

Answer. We have no information on the number of hotel owners who were fined or prosecuted.

Question. This is a horrible situation, and it must stop. Are effective steps now being taken to combat fraud and abuse by owners of welfare hotels?

Answer. We understand that New York City has taken a number of actions to combat fraud and abuse by owners of hotels. For example, a sophisticated computer system has been developed which provides for the daily reporting of families residing in a particular hotel or shelter. In addition, in the event of non-receipt of a check, workers are required to verify with hotel and bank staff as to whether or not a check was issued to a homeless family.

Question. I know the McKinney Homeless Act mandates that you report to Congress by July 1, 1989, on how to fix this problem. Can you tell us what steps you have taken to get the Federal government out of the welfare hotel business without throwing innocent families out on the streets? What actions do you plan in the future?

Answer. The Department published a Notice of Proposed Rulemaking (NPRM) on December 14, 1987 which we believed would address States' use of AFDC and Emergency Assistance funds to maintain AFDC recipients in welfare hotels. We felt that such a regulation would curtail the use of welfare hotels as long term housing for homeless families and prompt States to develop more effective, less wasteful alternative shelters. However, Congress

imposed a moratorium on final publication of the regulation; the moratorium expires on September 30, 1989.

We are currently reviewing the regulation and looking at other options which could diminish the use of welfare hotels and still ensure that homeless families will be provided with decent transitional shelter. We will include our recommendations in the report mandated by the McKinney Act. The report should reach Congress by the July 1, 1989 deadline.

Question. The Human Development Services budget includes $20 million to fully fund up to three demonstration programs authorized by the McKinney Act, to find alternatives to welfare hotels, but this would seem to put Secretary Sullivan into the housing construction business. Isn't there potential for fraud and abuse by putting the Department of Health and Human Services in charge of housing projects, or can this work be effectively coordinated through Secretary Kemp at HUD?

Answer. The demonstrations are limited in duration -- not ongoing -- focused on transitional facilities in a maximum of three States, and also intended to explore whether providing social services can help achieve the transition to permanent housing. Given this latter goal in particular, it is not inappropriate for the demonstrations to be overseen by this Department. Moreover, we believe that with proper oversight and administrative controls and coordination with the appropriate staff in HUD, the potential for fraud and abuse in these demonstrations will be minimized.

PREVENTING WASTE IN NEW JOBS PROGRAM

Question. Last month I held a hearing with Secretary of Labor Elizabeth Dole, and got her commitment to correct abuses which were wasting $26 million a year in job training entitlement program for welfare recipients, which allows States to enter into the same kinds of on-the-job training contracts where problems have been discovered under the Labor Department's Job Training Partnership Act. With first-year funding of $350 million, your welfare "JOBS" program is expected to exceed $1 billion by fiscal 1991. Will you work closely with the Labor Department, not only to prevent duplication and overlap, but to avoid their mistakes of the past?

Answer. Yes, we have been and will continue to work closely with Labor and other Departments as we implement the JOBS program. When we were developing the proposed regulations for the Family Support Act, we coordinated our actions with the Labor, Education, and Interior Departments as well as with many State and local representatives. Whenever possible, we have taken steps to ensure that our programs have compatible rules and do not overlap funding. When outlining means of implementation for the proposed rules, we believe that we have streamlined and simplified some prior practices. We continue to study others.

Question. Part of the problem at the Labor Department over the past few years has been the lack of sufficient Federal guidelines, monitoring, and technical assistance. This "hands off" attitude has unfortunately increased the opportunity for

fraud and abuse. As you gear up for this major new job training program, do you plan to take an active role from the start, or simply let the State "re-invent the wheel" with minimal Federal guidance?

Answer. Individual States will be responsible for the day-to-day management of the JOBS program. HHS will offer technical assistance to States and, we believe, most States will use our services to focus and improve their programs. Setting up Federal guidelines for States and monitoring State progress requires a great deal of thought and discussion. During the period in which we wrote the proposed regulations for the JOBS program, we conferred with representatives from all levels of State and local governments, as well as special interest groups. We expect to continue to foster the State/Federal partnership in order to ensure that Federal dollars are appropriately expended while continuing to give States a great deal of flexibility in program design.

LIHEAP CUTS

Question. Since 1986, the LIHEAP appropriation has been continually reduced from $2 billion to about $1.4 billion in fiscal year 1989. You are requesting another cut of $283 million for fiscal year 1990, which would reduce the appropriation to $1.1 billion. What actions are states taking to maintain levels of funding for LIHEAP, such as changing the levels of funds transferred to or from other block grants, or adopting alternative strategies and sources of funding?

Answer. Between FY 1987 and FY 1988 there was a $288 million (16 percent) reduction in federal net allotments to states. In FY 88, States supplemented federal LIHEAP net allotments with $159 million in oil overcharge funds and $17 million in state and other funds. These actions offset about 60 percent of the reduction.

Some program components which are governed by statutory limits find that lowering appropriations reduces the size of these components; e.g.

- There was a $26 million decrease in the amount of LIHEAP transfers to other HHS block grant programs.
- There was a $52 million decrease in LIHEAP carryover to the following fiscal year.
- There was a $20 million decrease in LIHEAP administrative costs.

In FY 1988, however, states still transferred a total of about $66 million in LIHEAP funds to other HHS block grants, and no states transferred funds from other block grants into LIHEAP.

Question. What impact have funding reductions had on the percentage of the eligible population being served and the percentage of energy costs covered?

Answer. State-reported data on numbers of households served show that the proportion of the households eligible for LIHEAP

assistance under the federal maximum income standards which received LIHEAP assistance with heating costs was 30% in FY 1985, 29% in FY 1986, 28% in FY 1987, and 25% in FY 1988. Using the actual state standards of eligibility, which are often below the federal maximum, 37% of the eligible households received assistance with heating costs in FY 1986, 38% in FY 1987, and 35% in FY 1988. (The data reported for FY 1988 are preliminary. Data on the total number of households eligible at federal and state eligibility standards are developed from the March Current Population Survey.)

The average percentage of energy costs covered has actually increased between FY 1985 and FY 1987. The Low Income Home Energy Assistance Annual Reports to Congress for fiscal years 1985, 1986, and 1987 indicate that energy assistance payments offset 57% of the average heating bill in FY 1985, 57% in FY 1986, and 61% in FY 1987.

Question. What changes are apparent in the types of clients being served; that is, are reductions affecting any particular groups of recipients to any greater degree?

Answer. We do not have data on who receives LIHEAP assistance nor do we have any data on who applies. We are following up on what appears to be evidence that fewer households are applying for assistance now that the percent of income paid for heat has decreased so much. Whether because of changes in who applies for LIHEAP, or changes in state's policies, LIHEAP appears better targeted. States are required to report annually on the income levels and presence of elderly and handicapped members in households receiving LIHEAP assistance. A comparison of these data for FY 1985 (the year of greatest federal funding) and FY 1988 for heating assistance indicates:

- The percent of households with incomes over $15,000 increased from 1.4 percent to 2.2 percent.
- The percent of heating assisted households with one or more elderly members increased slightly from 33.3 to 33.9 percent.
- The percent of heating assisted households with one or more handicapped members increased from 14.2 to 16.1 percent.

A comparison of data derived from national household surveys which include a set of energy assistance questions allows for longitudinal study of certain household characteristics.

- Energy assistance recipients with household incomes below 75% of the Federal Poverty Income Guidelines have increased steadily from 40.6% of all eligible households in 1985 to 44% in 1988. This is accompanied by a reduction of 5% in energy assistance to households with incomes between 75% and 125% of poverty.
- The average household income of energy assistance recipient households has always been lower than that of non-recipient low income households. In 1986 an energy

assistance household's average income was 83.5% of the income of all eligible households; in 1988, the recipient household income was 81.9% of the income of other low income households.

- o Energy assistance recipients of AFDC and SSI households is up slightly from 1986 to 1988.

- o Fewer energy assistance households heat with electricity in 1988 (11%) than did in 1985 (14.3%). This is in contrast to the increase noted in electric heat as the main heating fuel for all other households between 1985 and 1988.

OIL OVERCHARGE FUNDS

Question. What is your current estimate of the total petroleum overcharge distributions to be made to States for fiscal years 1989 and 1990, and for future years?

Answer. Based on our communications with DOE, approximately $350 million will be distributed to the States in FY 1989. This amount includes $127.3 million so far distributed in FY 1989. The $127 million, all Stripper Well funds, includes:

- o $12.9 million - first distribution of Texaco funds on 11/3/88

- o $81.0 million - Getty funds (on 4/6/89)

- o $33.4 million - other Stripper Well funds

Approximately $90 million in additional Texaco funds are expected in FY 1989. Based on the above information, we know of approximately $218 million and expect about $132 million more in FY 1989, most likely from Stripper Well settlements.

Under terms of the settlement reached last year, Texaco agreed to pay $1.25 billion to DOE over a 6 year period, beginning in FY 1989. This timetable will result in a second payment to DOE of $190 million, plus accrued interest, in FY 1990. Beginning one year thereafter, Texaco will make four equal annual installments of $165 million, plus accrued interest. Presumably, each one of these payments will be reduced by 20% to be withheld by the Office of Hearings and Appeals (OHA) for a claims procedure, before being split evenly between the Federal and State governments. States, if they so choose, will be able to apply their share of the funds toward their LIHEAP programs.

Based on the Texaco formula, States can expect to see approximately $350 million as their share of this settlement from FY 1990 through FY 1994. It is likely that $76 million in Texaco funds will be distributed to states in FY 90, with $66 million per year through FY 94.

The Department of Health and Human Services does not control and cannot predict the date of actual distribution of additional oil overcharge funds. The Department of Energy is the source for information and estimates regarding the amount and distribution

schedule of future settlements. The $350 million that States are expected to receive in FY 1989 represents monies from Texaco, DOE's Deposit Funds Escrow account, and several court escrow accounts. It should be noted that this amount is an estimation and could vary since these funds are generated by court orders and voluntary settlements, which are not controlled by either DOE or HHS.

DOE estimates remaining collections in petroleum overcharge cases will total $750 million to $1.25 billion. This estimate, does not include amounts which would be realized from Texaco. Actual collection amounts depend upon the litigation results in the remaining cases, as well as those firms' financial conditions at the time collection is attempted. If the future collections follow the Stripper Well agreement, approximately 40% of the monies collected would be distributed to the States.

The majority of States still have oil overcharge funds received under the Exon, Diamond Shamrock, and 14 Stripper Well settlement distributions.

Question. To what extent, if any, have States indicated any change in the proportion of these funds they are designating for the Low Income Home Energy Assistance Program?

Answer. The States have discretion over which programs receive oil overcharge funds. In telephone surveys conducted by the Family Support Administration (FSA) in HHS, the States have reported using about $370 million in oil overcharge funds for their LIHEAP programs from FY 1986 through FY 1988. This includes $160 million in oil overcharge funds the States distributed through LIHEAP in FY 1988. States have reported to DOE designating about $400 million for LIHEAP, as of April 6, 1989.

More States are beginning to channel their remaining and future oil overcharge distributions to LIHEAP to respond to the reduction in Federal appropriations. However, there has been no significant upward or downward change in the overall percentage of funds going for State LIHEAP programs. The proportion of funds allocated for LIHEAP has remained fairly consistent in each fiscal year since 1983, based on the total amount of funds distributed and available at the time.

Of the $2.5 billion in combined Exxon and Stripper Well funds so far designated by States, approximately 15%-16% has been designated for LIHEAP.

Question. How much of the available petroleum overcharge funds do you anticipate States applying to the Low Income Home Energy Assistance Program in fiscal year 1990?

Answer. We expect state governments will adjust their use of overcharge funds according to a combination of Federal appropriations and what they perceive as the primary needs in their states. If states followed recent practices 20% of the undesignated Exxon funds would be allocated to LIHEAP, or $80 million; 10% of the remaining Stripper Well funds, or $27 million; and 10% of the future Stripper Well distributions in FY

1990 (i.e., Texaco), or $10 million plus other distributions that may occur. Therefore, we estimate that if States continue to allocate the same percentage of oil overcharge funds to LIHEAP as they have in the past, then almost $120 million in oil overcharge funds could be allocated for energy assistance in FY 1990. Additional funds may be allocated for future years; some States have already made such allocations for future years.

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SUPPLEMENTAL FOR REFUGEE ADMISSIONS

Question. President Bush has submitted a $200 million supplemental request for the State Department to process increased refugee admissions. This is based on raising the refugee admission ceiling from 84,000 to 112,500 persons, including an additional 24,500 admissions from the Soviet Union.

Why is there no corresponding increase in your budget to resettle these refugees once they reach our shores?

Answer. We plan to submit a request for reprogramming funds from Cash and Medical to Voluntary Agencies to resettle these refugees.

Question. Is it fair to let the States bear the cost of refugee admissions policies of the United States Government?

It appears the Bush budget would impose a 1.1 percent cut on the fiscal 1989 refugee resettlement program, in order to pay for a package of supplementals including the State Department refugee assistance.

Answer. The Refugee Resettlement account would be exempt from the proposed 1.1% cut on FY 1989 discretionary programs.

Question. What would be the impact of this $4 million cut, with the fiscal year more than half over?

Answer. The Refugee Resettlement program would be exempt from the proposed 1.1% cut on FY 1989 discretionary programs.

Question. Explain the rationale behind cutting domestic refugee resettlement funding to pay for expansion of refugee admissions to this country.

Answer. The additional $100 million requested for State Department costs of bringing more refugees into the country could not be funded through a reduction to domestic program funding.

REFUGEES ON WELFARE

Question. According to the Congressional Research Service, recent studies indicate 52 percent of refugees in the United States less than 31 months were on the welfare rolls. The dependency rate was highest in California (77 percent), where cost assistance payments are the most generous.

Don't you find this dependence on welfare disturbingly high?

Answer. As of September 30, 1988, the dependency rate among refugees who had been in the U.S. less than 24 months was 52.1%, and the rate in California was 78.9%. The average for all other States was 33.2%.

We have been concerned for several years about dependency in the States with higher rates of use of cash assistance. This concern led to the establishment in 1985 of a Refugee Demonstration Project (RDP) in California and a Refugee Early Employment Project (REEP) in Oregon under the authority of the Wilson/Fish Amendment to the Refugee Act. During the operation of these projects, the dependency rate in California was reduced from 90.4% of refugees who had been in the U.S. less than 36 months as of September 30, 1985, to the 78.9% referred to previously. In Oregon during the same period, the rate was reduced from 64.1% to 50.1%.

The same concern led us to initiate a Key States Initiative in 1987 in five other States with dependency problems. These efforts have been similarly directed toward employment and reduction in dependency.

Question. Are you concerned that we may be building a welfare mentality in otherwise capable and industrious people?

Answer. Yes, that is why the Administration's policy has reduced the number of months of 100 percent Federal reimbursement for cash and medical assistance.

Question. What actions can you suggest to better gear the refugee resettlement program toward fostering self-sufficiency?

(Background: Most of the Refugee appropriation--$261 million out of $382 million--is for cash and medical assistance. The Congressional Research Service notes that some experts in this field have suggested a separation of refugee social services from the expensive, sometimes counter-productive, welfare programs.)

Answer. The Refugee Demonstration Project and the Refugee Early Employment Project constitute efforts to determine to what extent changes in regular welfare rules and special efforts at job training and placement can lead to beneficial results, both for the refugees involved and in terms of reduced expenditures of

public funds. Careful evaluations of these projects are underway.

It should be noted that most refugees who receive assistance are under the program of Aid to Families with Dependent Children (AFDC). A much smaller number are recipients of supplemental security income (SSI) for the aged, blind, and disabled. The eligibility of refugees for these regular welfare programs is established by law and exists independently of the availability of special Federal refugee funding. We hope that the new JOBS program for AFDC recipients under the Family Support Act of 1988 will be of significant help to refugee as well as non-refugee AFDC recipients in becoming employed and self-supporting.

The only special eligibility of needy refugees for assistance is during a refugee's first 12 months in the United States when a refugee who meets the same financial need for assistance as in a State's AFDC program can receive the same amount of assistance even though the refugee does not meet AFDC family-composition requirements. This program of refugee cash assistance (RCA), financed entirely with Federal refugee funds, provides a transitional safety net during a refugee's initial period in the U.S.

In addition, we hope that the Administration's policy to reduce the number of months of reimbursement will encourage states to develop effective and innovative methods for reducing refugee welfare dependency.

IMPROVING CHILD SUPPORT COLLECTIONS

Question. Last fall, the HHS Inspector General's Office estimated that $226 million could be saved through improved child support enforcement collections. One recommendation would require States to annually match the Social Security numbers of absent parents against earnings records, to identify parents who aren't paying, but could afford to. What is being done to implement these recommendations?

Answer. OCSE in cooperation with SSA and IRS is matching absent parent Social Security Numbers against wage and asset information to identify absent parent resources which are available to pay child support. In proposed rules published on April 19, 1989, States will be required to match unlocated or unenforced cases against State wage and unemployment data quarterly.

Question. Specifically, what is being done to see that States do a better job of: systematically reopening child support cases that did not produce a court order; attempting to modify low support orders; and pursuing collection of arrearage and wage withholding?

Answer. The following efforts are being made to see that States do a better job of:

1. Systematically reopening child support cases that did not produce a court order.

Proposed regulations were published April 19, 1989, in response to the requirement in section 121 of P.L. 100-485 that the Department publish regulations setting requirements for prompt State response to requests for child support assistance. Under those proposed rules, States would be required, if the court or administrative authority dismisses a petition for a support order without prejudice, to examine the reasons for dismissal, determine when it would be appropriate to seek an order in the future, and seek an order at that time. In addition, quarterly matching is required to obtain location and employment information. These regulations also establish criteria which must be met before a child support case may be closed.

2. Attempting to modify low support orders.

Regulations are about to be published implementing the requirement in section 103 of P.L. 100-485, effective October 13, 1989, that use of guidelines to establish support orders be a rebuttable presumption in establishing all orders in a State. Mandatory application of guidelines will ensure that support award amounts will be adequate to meet the needs of children. Section 103 further requires, effective October 1, 1990, that States establish a plan for periodic review and modifications of orders, in accordance with the State's guidelines at the request of either party. More specific requirements are effective in 1993. Our proposed regulations implementing this requirement will require that inconsistency with the State's guidelines for support must be adequate grounds for modification of an order.

3. Pursuing collection of arrearage and wage withholding.

Current initiatives to use liens and credit reporting and regulations establishing time frames for States to provide child support services will significantly impact State performance in providing enforcement services under the program. In addition, regulations under development to implement the requirement in section 101 of P.L. 100-485 for immediate income withholding will increase the number of child support cases subject to withholding.

Question. How cooperative has the Internal Revenue Service been in establishing ongoing matching operations to identify absent parents who are able to pay child support?

[Background: The IG study found 27 percent of absent parents with AFDC dependents earned more than $10,000 per year and could afford to pay child support. From estimated collections of $317 million for AFDC collections and $617 million for non-AFDC collections, total Federal savings would top $226 million annually.]

Answer. IRS has been cooperative in providing expanded wage and employer information in the ongoing matching operations.

CURTAILING CHILD SUPPORT INCENTIVE PAYMENTS

Question. You have proposed legislation to save $47 million in FY 1990 by limiting incentives to States on child support

collections only to States that demonstrate a cost effectiveness ratio of 1.4 or better. Which States do you anticipate would lose funding under this proposal? My own State of Iowa returns $1.82 for every Federal dollar spent on child support enforcement activities; yet a number of States returned less than 50 cents on the dollar.

Answer. With improvements in the effectiveness and efficiency of their child support program, no State need lose any funding under this proposal. However, if performance only attains the most recent State projections, 25 States would lose funding based on the fact that AFDC collections to Total expenditures are expected to be below 1.4 in FY 1990. There are five States that would lose the Non-AFDC incentive based on FY 1990 estimates. Three States lose incentives for both AFDC collections and Non-AFDC collections. The total number of States losing incentives is 27. They are:

AFDC INCENTIVE	NON-AFDC INCENTIVE	BOTH INCENTIVES
ALABAMA	D.C.	D.C.
ARIZONA	GUAM	GUAM
COLORADO	MISSISSIPPI	MISSISSIPPI
DELAWARE	NORTH DAKOTA	
D.C.	WEST VIRGINIA	
FLORIDA		
GUAM		
HAWAII		
ILLINOIS		
KANSAS		
KENTUCKY		
LOUISIANA		
MARYLAND		
MISSISSIPPI		
NEBRASKA		
NEVADA		
NEW JERSEY		
NEW YORK		
OKLAHOMA		
OREGON		
PENNSYLVANIA		
TEXAS		
UTAH		
VIRGIN ISLANDS		
VIRGINIA		

In FY 1988, Iowa had a cost effectiveness ratio of $3.22 for AFDC collections to total expenditures. This was substantially greater than the national average which was $1.27. The Non-AFDC collections to total expenditures ratio was $1.50 for Iowa. The national average was $2.67.

Question. Why is there such a wide variation among States in Federal costs for child support enforcement activities, compared to collections?

[Background: This legislative proposal would reduce the $294 million FY 1990 budget to $247 million, compared to $260

million estimated for FY 1989 incentive payments. States, such as New York and California cost the Federal government millions more than they collect in child support.]

Answer. We have attached copies of three tables that show tentative FY 1988 child support collections per dollar of administrative expenditures. These tables show the relationship of total collections to total expenditures; AFDC collections to total expenditures; and Non-AFDC collections to total expenditures. The data indicates that in fiscal year 1988, the Child Support Enforcement program collected $3.94 for every dollar spent on State and local program administration.

A substantial part of the variation among States is due to differential use of efficient techniques and wide differences in effective case management. Despite the potential efficiencies implicit in the 1984 Child Support Enforcement Amendments and their further elaboration in the Family Support Act of 1988, many States continue to follow cumbersome, expensive and ineffective techniques in location, and in establishment and enforcement of orders. OCSE continues through training and technical assistance efforts to persuade inefficient States to take advantage of better and more economical ways of doing things. Where States have failed to comply with new requirements intended to improve effectiveness and efficiency, OCSE audits have documented that fact and penalties have been imposed.

TOTAL CHILD SUPPORT COLLECTIONS PER DOLLAR OF TOTAL ADMINISTRATIVE EXPENDITURES

STATE	1986	1987	1988
ALABAMA	2.05	2.09	2.90
ALASKA	2.61	3.05	3.46
ARIZONA	1.46	2.21	2.11
ARKANSAS	2.62	2.94	2.94
CALIFORNIA	2.37	2.52	2.75
COLORADO	1.89	1.90	1.99
CONNECTICUT	3.49	2.91	2.73
DELAWARE	2.46	3.07	2.62
DISTRICT OF COLUMBIA	0.92	0.97	1.21
FLORIDA	2.12	1.90	2.20
GEORGIA	2.59	3.16	2.80
GUAM	1.39	1.53	1.62
HAWAII	2.26	3.10	3.62
IDAHO	3.58	4.06	3.79
ILLINOIS	2.40	2.51	2.60
INDIANA	4.02	5.22	5.49
IOWA	6.77	6.12	6.36
KANSAS	2.15	2.50	2.51
KENTUCKY	2.52	2.59	2.44
LOUISIANA	1.99	2.20	2.60
MAINE	3.74	3.75	4.01
MARYLAND	3.77	3.02	3.31
MASSACHUSETTS	3.50	3.46	4.09
MICHIGAN	8.33	9.52	8.00
MINNESOTA	3.02	3.51	3.59
MISSISSIPPI	2.29	3.36	3.06
MISSOURI	3.89	4.35	4.22
MONTANA	2.39	3.16	2.97
NEBRASKA	5.44	5.20	5.02
NEVADA	2.10	2.30	1.99
NEW HAMPSHIRE	4.39	5.33	4.93
NEW JERSEY	4.64	4.47	4.12
NEW MEXICO	2.27	1.99	1.76
NEW YORK	1.83	1.90	2.36
NORTH CAROLINA	3.26	3.03	3.32
NORTH DAKOTA	2.46	2.65	3.14
OHIO	4.41	5.65	10.03
OKLAHOMA	1.78	2.22	2.48
OREGON	4.47	4.03	4.27
PENNSYLVANIA	7.78	7.56	8.51
PUERTO RICO	14.02	18.93	17.60
RHODE ISLAND	3.90	3.31	3.65
SOUTH CAROLINA	2.37	3.01	3.23
SOUTH DAKOTA	2.74	2.96	3.50
TENNESSEE	3.31	3.07	4.09
TEXAS	2.01	2.60	2.81
UTAH	2.21	2.39	2.86
VERMONT	2.34	2.95	3.31
VIRGIN ISLANDS	2.14	4.13	4.16
VIRGINIA	1.57	2.41	2.39
WASHINGTON	2.42	2.56	2.48
WEST VIRGINIA	1.98	2.00	2.16
WISCONSIN	4.78	6.20	6.01
WYOMING	3.27	4.64	4.91
NATIONWIDE TOTALS	3.45	3.68	3.94

AFDC/FC CHILD SUPPORT COLLECTIONS PER DOLLAR OF TOTAL ADMINISTRATIVE EXPENDITURES

STATE	1986	1987	1988
ALABAMA	1.09	1.01	0.89
ALASKA	0.57	0.75	0.98
ARIZONA	0.29	0.53	0.42
ARKANSAS	1.43	1.39	1.31
CALIFORNIA	1.21	1.27	1.36
COLORADO	1.11	0.94	0.93
CONNECTICUT	1.67	1.34	1.21
DELAWARE	0.88	0.92	0.89
DISTRICT OF COLUMBIA	0.49	0.58	0.56
FLORIDA	0.93	0.81	0.74
GEORGIA	1.57	1.44	1.26
GUAM	0.78	0.73	0.72
HAWAII	0.98	1.10	1.35
IDAHO	1.57	1.32	1.30
ILLINOIS	1.07	1.08	1.04
INDIANA	3.04	2.71	2.69
IOWA	4.34	3.51	3.22
KANSAS	1.35	1.41	1.02
KENTUCKY	1.01	0.93	1.05
LOUISIANA	0.80	0.90	1.05
MAINE	2.78	2.60	2.48
MARYLAND	1.24	0.85	0.90
MASSACHUSETTS	1.61	1.45	1.78
MICHIGAN	2.46	2.29	2.00
MINNESOTA	1.49	1.58	1.47
MISSISSIPPI	1.15	1.65	1.48
MISSOURI	1.32	1.49	1.29
MONTANA	1.93	2.00	1.78
NEBRASKA	0.93	0.85	0.75
NEVADA	0.67	0.62	0.53
NEW HAMPSHIRE	0.72	0.83	0.74
NEW JERSEY	1.17	1.07	0.99
NEW MEXICO	1.38	0.95	0.44
NEW YORK	0.68	0.75	0.80
NORTH CAROLINA	1.64	1.82	1.45
NORTH DAKOTA	1.65	1.78	1.65
OHIO	2.09	2.09	2.44
OKLAHOMA	0.99	0.97	1.00
OREGON	1.39	1.11	1.10
PENNSYLVANIA	1.49	1.28	1.44
PUERTO RICO	0.41	0.32	0.41
RHODE ISLAND	2.20	1.78	1.83
SOUTH CAROLINA	1.15	1.19	1.01
SOUTH DAKOTA	1.64	1.44	1.51
TENNESSEE	1.03	0.97	1.51
TEXAS	0.82	0.84	0.92
UTAH	1.20	1.13	1.26
VERMONT	1.84	2.14	2.26
VIRGIN ISLANDS	0.22	0.33	0.35
VIRGINIA	0.87	0.64	0.57
WASHINGTON	1.32	1.36	1.23
WEST VIRGINIA	1.86	1.16	0.75
WISCONSIN	2.11	2.30	1.96
WYOMING	1.67	2.14	2.09
NATIONWIDE TOTALS	1.30	1.27	1.27

NON-AFDC CHILD SUPPORT COLLECTIONS PER DOLLAR OF TOTAL ADMINISTRATIVE EXPENDITURES

STATE	1986	1987	1988
ALABAMA	1.36	1.48	1.41
ALASKA	2.04	2.29	2.47
ARIZONA	1.17	1.48	1.69
ARKANSAS	1.20	1.39	1.44
CALIFORNIA	1.16	1.26	1.38
COLORADO	0.79	0.95	1.06
CONNECTICUT	1.82	1.96	1.92
DELAWARE	1.66	2.15	1.83
DISTRICT OF COLUMBIA	0.43	0.47	0.65
FLORIDA	1.17	1.17	1.35
GEORGIA	1.01	1.30	1.42
GUAM	0.61	0.80	0.99
HAWAII	1.27	1.99	2.06
IDAHO	2.01	2.35	2.30
ILLINOIS	1.33	1.42	1.64
INDIANA	1.77	2.31	2.00
IOWA	2.43	2.61	3.14
KANSAS	0.00	1.17	1.30
KENTUCKY	1.51	1.66	1.39
LOUISIANA	1.10	1.30	1.35
MAINE	1.04	1.15	1.33
MARYLAND	2.53	2.10	2.41
MASSACHUSETTS	1.88	2.01	2.31
MICHIGAN	5.87	7.24	6.80
MINNESOTA	1.53	1.93	2.12
MISSISSIPPI	1.14	1.71	1.61
MISSOURI	2.56	3.06	2.93
MONTANA	0.67	1.17	1.19
NEBRASKA	4.52	4.35	4.20
NEVADA	1.43	1.67	1.48
NEW HAMPSHIRE	3.67	4.30	4.10
NEW JERSEY	3.47	3.48	3.13
NEW MEXICO	0.89	1.05	1.32
NEW YORK	1.15	1.23	1.48
NORTH CAROLINA	1.62	2.00	1.87
NORTH DAKOTA	0.82	0.95	1.29
OHIO	2.31	3.36	0.39
OKLAHOMA	0.79	1.25	1.47
OREGON	3.08	2.92	3.17
PENNSYLVANIA	6.39	6.20	7.07
PUERTO RICO	13.61	18.42	17.19
RHODE ISLAND	1.70	1.61	1.82
SOUTH CAROLINA	1.22	1.83	2.22
SOUTH DAKOTA	1.10	1.52	1.99
TENNESSEE	2.28	2.10	2.30
TEXAS	1.19	1.76	1.89
UTAH	1.01	1.26	1.60
VERMONT	0.59	0.82	1.05
VIRGIN ISLANDS	1.91	3.00	3.01
VIRGINIA	0.70	1.70	1.82
WASHINGTON	1.09	1.20	1.24
WEST VIRGINIA	0.12	0.84	1.41
WISCONSIN	2.66	3.90	4.04
WYOMING	1.61	2.50	2.83
NATIONWIDE TOTALS	2.15	2.41	2.67

FEDERAL LOSS UNDER CHILD SUPPORT ENFORCEMENT

Question. Collections from absent parents under the Child Support Enforcement Program have never been sufficient to fully offset Federal costs of this program. When do you expect this program to pay for itself, and actually start returning more than it costs to the Federal government?

Answer. Under current law, as the program is now financially structured, this program is unlikely anytime in the immediate future to return more to the Federal government than it costs. Reduction of the Federal deficit under the financial structure imposed by current law would require States to operate

much more cost effectively. Greater returns relative to dollars spent will improve the financial position of both the States and the Federal government. Because, the Federal government pays 23 percent of its share of AFDC collections (and potentially 30 percent) to the States as incentives, the portion it retains must be larger than the Federal share of administrative costs (66 percent, beginning in FY 1990) or the Federal government loses money. The $50 pass through provision enacted in 1984 also currently passes on to AFDC families $263 million a year which previously was returned to the Federal government. President Reagan's FY 1990 Budget proposed to remove the protective floor on incentive payments in a step which would stimulate improved program performance while concurrently reducing federal deficits in the program.

Enforcement efficiencies mandated by the Child Support Enforcement Amendments of 1984 and the Family Support Act of 1988 would also help to achieve the levels of cost effectiveness necessary to reduce federal deficits. However, States have not taken full advantage of these tools. Audit penalties threaten the States with financial consequences unless they proceed to undertake the necessary steps which will provide both more effective child support services to America's children. If States substantially improve the cost-effectiveness of their AFDC collections efforts, then the Federal deficit in this program will be reduced. Increases in the cost-effectiveness of the non-AFDC portion of the program, however, could actually increase the Federal deficit by increasing the amount of incentives paid from the Federal share to States.

Question. Why should the States be allowed to profit from this program, while the Federal government absorbs growing losses?

Answer. States profit from the program while the Federal government loses money because of the statutory construction of the financing arrangements for the Child Support Enforcement program. There needs to be a more equitable funding arrangement which encourages States to perform more cost effectively and rewarding States that do. The incentive payments were established to encourage and reward State child support enforcement programs which perform in a cost-effective and efficient manner. However, the current incentive structure is overly generous, rewarding States regardless of what they spend to achieve collections. The administration's proposed legislation would begin to redress this by discontinuing the practice of awarding incentive payments to States whose performance is clearly substandard. This would reduce the amount of the incentives paid out of the Federal share of collections to States by the Federal government.

COMMUNITY SERVICES BLOCK GRANT

Question. If we abolish Community Action Agencies, wouldn't we simply have to create replacement agencies to run programs such as Head Start and Low Income Home Emergency Assistance?

Answer. To our knowledge no one has proposed abolishing CAAs. These locally created entities receive financial support

to administer numerous programs from other Federal, State, and private agencies and organizations.

Even if budget negotiations resulted in reduced CSBG funding, the effect on community action agencies (CAAs) should be modest. The precursor to the CSBG helped community action agencies get started. CAAs now administer many programs, including many Federal programs. As a result of their success, CAAs depend on the CSBG for about 12% of their resources. Now, the CSBG pays for additional administrative overhead that might otherwise be allocated to specific programs (perhaps 40% of the CSBG) and services for which States have not provided Social Services Block Grant funds. In addition, over $40 million in FY 1989 CSBG appropriations were earmarked for direct Federal grants that do not fund these services by CAAs. By including the CSBG in the residual category, the Administration has indicated its readiness to discuss with Congress the avenues through which Federal funds are given to CAAs.

Question. Isn't it true that Community Action Agencies leverage a significant amount of State and local funds and make extensive use of volunteers?

Answer. Community Action Agencies are sub-state grantees and States are not required to report data on the amount of State and local funds leveraged or the use of volunteers.

AFDC FRAUD PREVENTION

Question. The Family Support Act of 1988 requires States to provide appropriate measures to detect fraudulent AFDC applications before the family's eligibility is established. It appears the States will receive 50 percent Federal matching funds for such pre-eligibility fraud detection measures.

The Omnibus Budget Reconciliation Act of 1987 allows States to establish a fraud control program. Under such a program, persons (applicants or recipients) who are found to have intentionally misrepresented the facts to qualify for or remain on AFDC are ineligible for AFDC for a period of 6 months for the first offense, 12 months for the second offense, and permanently for the third and subsequent offenses. States that chose to operate a fraud control program receive 75 percent Federal matching funds for such expenditures.

Is it true that the pre-eligibility fraud detection program receives only 50 percent Federal reimbursement whereas a State's fraud control program receives 75 percent Federal reimbursement? Why?

Answer. It is correct that under the law the Federal reimbursement match is 50 percent for pre-eligibility fraud detection activities and 75 percent for the optional AFDC fraud control program. There is currently no statutory authority to provide enhanced matching for pre-eligibility fraud activities, many of which are simply additional tasks assigned to intake workers as part of the eligibility process. These tasks differ from those carried out if the case is then referred to the fraud control unit staff. The fraud control unit's work is authorized

under section 416 of the Social Security Act and matched at the enhanced rate.

Question. Is it true that a person found guilty under the pre-eligibility fraud detection program could reapply for AFDC benefits the next day or the next month? What is the rationale behind spending an estimated $94 million on such a program in fiscal 1990 if there is no standard disqualification period?

Answer. It is true that in States without the optional fraud control program, a person found guilty only under the pre-eligibility fraud detection program will not be penalized by a disqualification period. There can be no standard disqualification period in the absence of a disqualification hearing procedure or court action, both of which provide safeguards to protect the AFDC recipient's rights. These procedures are initiated under the optional fraud program, which seeks to establish a determination of intentional program violation(s). However, they are not initiated under the pre-eligibility program, which only provides a basis either to deny AFDC eligibility or a referral for follow-up by the fraud control unit. Nonetheless, the pre-eligibility fraud program continues to make sense both as a deterrent and as a means of identifying potential fraud at the front end, before it actually occurs.

LOW INCOME HOME ENERGY ASSISTANCE

Question. To what degree are States now concentrating Low Income Home Energy Assistance funding on what some see as the program's "core" mission: helping pay for home energy costs? Do you see a significant trend toward paying for these costs and concentrating resources on the elderly or very poor, as opposed to weatherization, transfers to other block grants and administration?

Answer. We see no significant change. Using FY 1985 (the year of highest federal funding) as the base year and state estimates of total uses of LIHEAP funds, the estimated percentage of total uses of LIHEAP funds obligated by states for fuel assistance (i.e., heating, cooling, and crisis assistance) is as follows based on the results of HHS' LIHEAP telephone surveys:

Fiscal Year	Percentage
1985	75
1986	74
1987	71
1988	74

The percent of LIHEAP funds used for fuel assistance has remained fairly stable since FY 1985. A trend analysis of fuel assistance benefits going to the elderly or very poor is not possible as States are not required to report data on the dollar amount of fuel assistance benefits being provided to elderly households or to various income groups. However, between FY 1985 and FY 1988, the percent of heating assisted households with one or more elderly members increased slightly, from 33.3 to 33.9 percent.

Based on the results of HHS' LIHEAP telephone surveys, there have been no major shifts in the distribution of funds for weatherization, transfers, or administrative costs as seen below:

Percent of total uses of funds by fiscal year[1]

	1985	1986	1987	1988
Weatherization assistance	10%	9%	10%	9%
Transfers	4	4	4	4
Administrative costs	7	8	8	8

Weatherization assistance is provided for in the LIHEAP statute and helps recipient households to meet their home energy costs.

[1]Includes federal net allotments, carryover from previous fiscal year, oil overcharge funds, and state and other funds.

STATES COMMITMENT OF FUNDS

Question: Are States reducing the commitment of funds "across-the-board," or concentrating reductions in specific program components (for example, administration and transfers to other block grant programs)?

Answer: A comparison of the distribution of funds across LIHEAP program components for FY 1985 (the year of highest federal funding) and FY 1988 indicates:

Percent of total uses of funds[1]

	FY 1985	FY 1988
Benefits[2]	85%	84%
Administrative costs	7	8
Transfers	4	4
Carryover	4	4

Overall, it appears that the distribution of funds for benefits has decreased slightly to offset a slight increase in administrative costs. Also, the distribution of funds for transfers and carryover overall has remained the same.

[1]Includes federal net allotments, carryover from previous fiscal year, oil overcharge funds, and state and other funds.
[2]Includes heating, cooling, crisis, and weatherization assistance.

Question. Has there been a noticeable shift in States' allocations of their Federal appropriations for the Low Income Home Energy Assistance Program in response to cutbacks in recent years?

Answer. No. States' estimates of their total uses of funds across LIHEAP program components from FY 1985 through FY 1988 is as follows:

Percent of total uses of funds by fiscal year[1]

	1985	1986	1987	1988
Benefits[2]	85%	83%	82%	84%
Administrative costs	7	8	8	8
Transfers	4	4	4	4
Carryover	4	5	6	4

It appears that the distribution of LIHEAP funds has remained stable for transfers and fairly stable for administrative costs. The distribution of funds for benefits and carryover has fluctuated slightly.

[1]Includes federal net allotments, carryover from previous fiscal year, oil overcharge funds, and state and other funds.
[2]Includes heating, cooling, crisis, and weatherization assistance.

Question. Specifically, to what extent have States reduced their allowed carryovers to later fiscal years and allocations to other Federal block grant programs in order to shore up current-year spending?

Answer. The percent transferred to other block grants has remained the same. The percent carried over in FY 88 was the same as the percent carried over in FY 85, the year of greatest funding.

Question. To what extent have funds transferred from the Low Income Home Energy Assistance Program contributed to funding of other federally supported block grant initiatives such as the social services block grant?

Answer. Each year, states transfer about the same portion of funds to other block grants. In fiscal year 1988, 28 states transferred a total of about $66 million in LIHEAP funds to other block grants administered at the federal level by the Department of Health and Human Services. The breakdown of funds transferred is approximately as follows: Social Services Block Grant: $49.4 million; Community Services Block Grant: $10.4 million; Maternal and Child Health Services: $5.7 million; Alcohol and Drug Abuse and Mental Health Services: $.4 million; Preventive Health and Health Services: $.1 million.

Each year under the LIHEAP block grant, between 28 and 33 states have transferred between $66 million and $115 million to other HHS block grants. Each year 70 to 85 percent of the transferred funds have gone to the Social Services Block Grant. This suggests states place lower priority on LIHEAP.

OIL OVERCHARGE FUNDS

Question. How much remained in the Department of Energy's oil price overcharge escrow account as of the end of fiscal year 1988? What portion of this amount is earmarked for disbursement to the States for use in energy-related programs such as the Low Income Home Energy Assistance Program?

Answer. The Department of Energy is the source for that information and can provide the most accurate figures on the amount of funds in its oil overcharge escrow account.

If future distributions follow the provisions of the Stripper Well agreement, then States will be able to use those funds for LIHEAP and the applicable DOE programs.

Question. Taking into account last summer's Texaco oil price overcharge settlement, any escrow amounts earmarked for disbursement to the States, and interest on amounts held in the Energy Department's escrow account, what new disbursements can States expect in fiscal year 1989 and 1990? To what extent are these disbursements dependent on States requesting them?

Answer. The Department of Health and Human Services does not control and cannot predict the date of actual distribution of additional oil overcharge funds. Based on our communications with DOE, approximately $350 million will be distributed to the States in FY 1989. This amount represents monies from Texaco, DOE's Deposit Funds Escrow account, and several court escrow accounts.

The $350 million amount includes $127 million so far distributed to the States, and an additional $90 million in Texaco money to be distributed in FY 1989. It should be noted that the $350 million is an estimation and could vary significantly since these funds are generated by court orders and voluntary settlements, which are not controlled by either DOE or HHS.

Based on the Texaco distribution formula, States can expect to see approximately $350 million as their share of this settlement from FY 1990 through FY 1994. This would include approximately $76 million to the States in FY 1990. More Stripper Well distributions are expected in FY 1990.

Because of the uncertain nature of pending court orders and settlements, States cannot affect the distribution schedule, nor request funds from specific overcharge settlements. Actual collection amounts depend upon the firms' financial conditions at the time collection is attempted. If the future collections follow the Stripper Well agreement, approximately 40% of the monies collected will eventually be distributed to the States.

CHILD SUPPORT ENFORCEMENT COLLECTIONS

Question. Although child support enforcement collections have increased from a little over $1 billion in FY 1978 to an estimated $4.7 billion in FY 1988, several studies report that potential collections may be closer to $20 billion. Is the $20 billion figure realistic?

Answer. With funding from OCSE, Dr. Ronald Haskins and associates at the University of North Carolina estimated the potential money available to absent fathers for child support. They used University of Michigan Income Dynamics Panel data on income and assets and applied the current Wisconsin and Delaware support order guidelines formulas to that income to determine

what portion should be collectible as child support for the 4 million or so fathers who are subject to support orders. In 1984 dollars, they found that $26.6 billion in potential child support should be available to the children of these fathers who are subject to support orders. This figure would be greater in FY 1989.

Question. How much of the recent increases in collections (since FY 1985) can be attributed to the 1984 provision requiring wage withholding in cases of overdue child support?

Answer. Total Child Support collections have increased by over $1.9 billion from FY 1985 to 1988. Wage withholding collections have increased by $1.6 billion during the same period. The wage withholding increases make up 84% of the total increase.

Question. How much impact do you think the 1988 provision requiring immediate automatic wage withholding will have on child support collections?

Answer. We believe that there will be minimal increase in the amount of child support collected through immediate wage withholding in FY 1990 for those States who did not have such authority in place prior to enactment of the Family Support Act. This provision is not required to be in effect until FY 1991. We believe that wage withholding will continue to be a substantial factor in the increase of child support collections. However, it is hard to estimate the impact of the immediate wage withholding provision since it is not required until FY 1991. Department estimates indicated cost savings of $8 million in each year beginning in fiscal year 1991.

CHILD SUPPORT ENFORCEMENT PATERNITY ESTABLISHMENT

Question. The Family Support Act requires States to determine the paternity of a specified share of children born outside of marriage who are receiving AFDC or child support enforcement services each year. States are to receive reduced Federal matching funds unless their paternity establishment percentage for a fiscal year is (1) 50 percent or greater, (2) equal to or greater than the national average, or (3) equal to what it was in fiscal year 1988), increased by 3 percentage points from fiscal year 1988 to fiscal year 1991, and by 3 percentage points each year thereafter. Do you think that States will be able to meet these new performance standards?

Answer. We believe that all States should be able to achieve the required increases. The Family Support Act provides States with additional resources for processing paternity cases. These include increased funding (90%) for genetic tests as well as the requirement that states must provide genetic tests in a contested paternity case. States may charge any party not receiving AFDC for the costs of the tests. States must also establish paternity for any individual who was under age 18 on August 16, 1984, regardless of whether a prior action for paternity establishment was dismissed because of a former statute of limitations.

Question. Why have States had such a poor record in establishing paternities?

Answer. OCSE has sponsored several studies that have looked at the establishment of paternity. Most of them suggest that the main reason that many State agencies show low proportions of paternities established is that they assign these cases low priority because of a perceived low collections potential. While research data does not support this belief, it has acted to hamper jurisdictions from aggressively establishing paternity.

CUT IN REFUGEE RESETTLEMENT FUNDS

Question. The fiscal 1990 budget request for the refugee resettlement assistance fiscal 1989 program represents a 37 percent reduction from the fiscal year 1989 appropriation.

Given the actual and potential sources of increased refugees (e.g., Soviet Jews, Armenians, and Nicaraguan Contra, possible resumption of negotiations with Vietnam regarding the release of political prisoners), is this realistic?

Answer. The FY 1990 budget request for refugee assistance is based on the same assumption as the Department of State's budget request -- namely, that 84,000 new refugees will be admitted to the United States in FY 1990. If the admissions ceiling, which is expected to be the subject of consultations between the Congress and the Executive Branch in September, differs from this projection, then we would need to look at the question of the need for revisions in FY 1990 funding.

REFUGEE TARGETED ASSISTANCE

Question. The 1988 Senate Appropriations Committee report indicated that it was the Committee's intent that targeted assistance funds be continued at current levels in all communities through calendar year 1989.

Why is no targeted assistance money requested when there is only sufficient existing money to continue funding at the current level through September 1989?

Answer. Most targeted assistance counties will have sufficient funds to carry them well beyond September 1989 when the FY 1989 targeted assistance allocations are made. However, our basic reason for not requesting additional funds for FY 1990 is the degrees of impact in FY 1980-1982 which gave rise to the targeted assistance program in FY 1983 no longer exist.

VOLUNTARY AGENCY PROGRAMS FOR REFUGEES

Question. The budget request for voluntary agency programs is $8 million, compared to $16 million in fiscal 1989.

What is the reason for this, in view of the fact that these programs are heavily used by Soviet refugees whose numbers are increasing significantly?

Answer. HHS is fully supportive of the voluntary agency matching grant program, as indicated by our proposal to reprogram nearly $22 million to that program in FY 1989 if the proposed increase in the refugee admissions ceiling is effected. At the time the FY 1990 Reagan budget request was developed (well in advance of the final determination of the numbers and countries of origina of FY 1990 arrivals, which is expected to be the subject of Congressional consultations next September), we believed that our $8 million request would allow us to fully fund the VOLAG program in FY90.

REFUGEE EMPLOYMENT SERVICES

Question. State-administered social/employment services funding would be decreased by more than half based on an estimated decrease in the eligible refugee population.

Is this a realistic estimate, given the fact that the number of refugees entering recently has, in fact, been increasing?

Answer. The Reagan request for $30 million for employment services -- previously termed "social services" -- does not reflect a capitation rate. Rather, it represents the amount which we believe can be appropriately requested insight of refugee needs, State support, and the Federal budget deficit. Non-time-eligible refugees would continue to be eligible to receive services, but ORR regulations emphasize the need to focus employment services on refugees who receive cash assistance, and whose employment would most reduce Federal and State public assistance costs.

REDUCING REFUGEE CASH AND MEDICAL ASSISTANCE

Question. The Immigration and Nationality Act authorizes 100 percent Federal reimbursement of cash and medical assistance for refugees during the first 36 months after entry. This period has now been reduced to 24 months by regulation, and the fiscal 1990 budget is based on a further reduction to 15 months. Isn't this contrary to the intent of the legislation?

Answer. The authorization of full reimbursement for cash and medical assistance during a refugee's first 36 months in the U.S. is contingent upon the availability of funds.

The 36-month limitation has not been reduced by regulation but according to the estimated duration for which appropriated funds are available. Thus the period was reduced to 31 months in March 1986 as a result of the Gramm-Rudman-Hollings reduction and to 24 months in February 1988 in accordance with the availability of funds under the 1988 Continuing Resolution. When the estimated period is below 36 months, all funds appropriated for cash and medical assistance will be made available to the States even if they exceed the estimated funding period, as long as they do not exceed 36 months.

AFDC FISCAL SANCTIONS

Question. Once again the Administration's budget assumes collection of fiscal sanctions for erroneous AFDC payments. The

budget assumes collection of $63 million in fiscal year 1989, $516 million in fiscal year 1990, $896 million in fiscal year 1991, and $735 million in fiscal year 1992. In addition, the Reagan budget proposed changes in the AFDC quality control system that are estimated to save $80 million in fiscal year 1990. Are these realistic assumptions given the fact that no collections for erroneous payments by States have ever been obtained by the Federal government?

Answer. These estimated collections are based upon statutory and regulatory requirements. The Congressional moratorium on collection of disallowances expires June 30, 1989. We intend to proceed with the process of collecting past period disallowances. It would be inappropriate for the Department to make an assumption that these past disallowances would not be collected, since current law has not been changed.

Question. Is it equitable to require payment of past-due fiscal sanctions given the probability of the implementation of a new quality control system with lower fiscal penalties? If a new system is adopted, why apply old rules to the arrearage?

Answer. Yes. Disallowances were properly established under rules and tolerances established by Congress. The 1989 bipartisan budget agreement provided for no new AFDC legislation, beyond the Family Support Act, that would increase the cost of the program. The collection of past period disallowances (FY 1981-1987) estimated at $1.5 billion is in the budget for subsequent years. Also, to retroactively recalculate past liabilities might be perceived as unfair by those States which actually met the statutory error allowance.

Question. Should the AFDC, Medicaid and Food Stamp programs have identical quality control systems?

Answer. There are many similarities between the programs and the system; however, the programs are different in a number of ways. They serve somewhat different populations; the goals, objectives and rules of the programs are different, and the legislative committee responsible for the rules and procedures are different. We have made major strides in integration of the QC data collection activities and systems. Significant future integration is dependent on greater compatibility of the program rules among the programs.

AFDC/JOBS PROGRAM

Question. One of the required components of the JOBS program enacted by the recent welfare reform law is educational activities, including basic literacy, and education for persons with limited English proficiency. How are States going to provide AFDC recipients with access to such activities?

Answer. The Statute requires that States make four mandatory elements available to participants in the JOBS program. These are 1) educational activities (as appropriate), 2) job skills training, 3) job readiness activities, and 4) job development and placement. In addition, States must provide two of the following four employment/training components: 1) job search, 2) on-the-job

training, 3) work supplementation, or 4) community work experience or any other work experience program approved by the Secretary. States must also provide supportive services, including child care (either directly or indirectly), as well as for other needs such as transportation, or one-time costs such as uniforms. We anticipate that State IV-A agencies will generally utilize educational activities already available, such as high school, GED and adult education programs, to provide this component to AFDC recipients.

Question. Will States use the high schools or community colleges?

Answer. We believe that this would be a very effective method for providing basic, remedial or supplemental education and training to JOBS participants.

Question. Will States primarily rely on the Job Training Partnership Act program to provide such activities for them?

Answer. Programs under the Job Training Partnership Act will be an important aspect of the JOBS program; however, these programs have a broader focus than the AFDC population. Under the Family Support Act, State IV-A agencies will have primary responsibility for development and provision of work, training, and education activities. They may utilize the expertise of State employment agencies, including contracting with such agencies for services. This is one of the areas in which we expect States to decide how best to use their resources.

Question. Will States make agreements with other agencies or organizations to provide the education activities?

Answer. States may use existing educational activities, such as high school, in the JOBS program. States may also make agreements, or even let contracts, for educational activities focused on JOBS participants. In order to prevent shifting the costs for such activities to the Federal government, the statute includes language which precludes Federal reimbursement for services and activities available to JOBS participants on a non-reimbursable basis. States are also required to expend an amount of funds equal to FY 1986 expenditures for education, training, and employment activities dedicated to assist AFDC recipients in becoming self-sufficient.

Question. In our hearing with Secretary of Labor Elizabeth Dole, she promised to look into ways to make better sense out of more than 40 Federal job training programs. Will you work closely with her to make sure the new JOBS program doesn't compound the problem of proliferation in Federal training programs?

Answer. We will cooperate with the Department of Labor to the fullest extent possible to ensure that our tax dollars are effectively spent. We intend to maximize the use of training programs under the JOBS program.

UNEMPLOYED PARENT PROGRAM

Question. Under previous law, States had the option of offering AFDC to children in two-parent families who were needy because of the unemployment of the principal earner. The Family Support Act requires all jurisdictions now without this program to make it available for at least 6 months (out of 12 months) to needy two-parent families in which the principal earner is unemployed, starting on October 1, 1990. What effect will this provision have on State budgets? Is this provision likely to shorten the length of time families spend on AFDC?

Answer. Under previous law, States had the option of offering AFDC to children in two-parent families who were needy because of the unemployment of the principal earner. The Family Support Act now requires that all jurisdictions without this program must make it available for at least 6 months (out of 12 months) to needy two-parent families in which the principal earner is unemployed effective on October 1, 1990.

This new provision will increase State budgets. However, in a demonstration project in Utah, we found that implementing a program with work activities, and payment after performance for a 6 month time-limited period, reduced expenditures 85% over prior UP programs in Utah. The average length of stay on AFDC decreased from 8 months to 8 weeks.

Historically, two-parent families receiving AFDC due to the unemployment of a parent have spent far less time on AFDC than those receiving benefits for other reasons. Such families have a more recent work history and better skills, thus possessing stronger ties to the work force. They generally are not in need of intensive work experience, education or training services; rather, they benefit most from either individual or group job search activities. Moreover, individual and group job search activities are the least expensive services for a work program to offer.

Question. How many States are likely to provide the new AFDC-UP benefit for more than the six months required under the law?

Answer. As of this time, we have received no feedback on what State planning will be with respect to this new requirement.

Question. What are the administrative implications of providing AFDC-UP benefits to a given family for only six months out of every 12-month period?

Answer. From an administrative standpoint, providing unemployed parent benefits to a given family for only six months out of every 12-month period will require verification of whether, when and for how long each family applying for those benefits last received assistance.

AFDC/ADMINISTRATION

Question. Currently, AFDC administration costs are matched on a 50 percent open-ended basis. The fiscal year 1990 budget proposes to cap AFDC administrative costs at the fiscal year 1989

level, with subsequent cost-of-living increases. How will the States respond to such a shift from open-ended funds to limited funds?

Answer. President Reagan's FY 1990 Budget proposed a cap on AFDC administrative costs at the FY 1989 level. We are not exactly sure how States will react to this change; however, we believe the vast majority of States would not suffer ill effects. It is hoped that states would become more efficient with the management of their AFDC programs.

JOBS BILL LANGUAGE

Question. You are asking for bill language to cap, at $350 million, the $801 million entitlement enacted by Congress last fall in the welfare reform bill for the JOBS program. What is the rationale for suggesting that the Appropriations Committee re-write the authorizing statute?

Answer. We have requested $350 million for the JOBS program for FY 1990. We believe this amount, which agrees with the Congressional Budget Office estimate of what States will spend to implement JOBS in FY 1990, will provide sufficient funding. Should this amount be inadequate, a supplemental appropriation would be needed.

Question. What would happen if we simply delete your language?

Answer. If the words "shall be the maximum" were deleted, States would have a legal claim to funding up to the $800 million entitlement cap.

FEDERAL LOSS UNDER CHILD SUPPORT ENFORCEMENT

Question. Collections from absent parents under the Child Support Enforcement Program have never been sufficient to fully offset Federal costs of this program. When do you expect this program to pay for itself, and actually start returning more than it costs to the Federal government?

Answer. Reduction of the Federal deficit under the financial structure imposed by current law will require States to operate much more cost effectively. Greater returns relative to dollars spent will improve the financial position of both the States and the Federal government. Because, the Federal government pays 23 percent of its share of AFDC collections (and potentially 30 percent) to the States as incentives, the portion it retains must be larger than the Federal share of administrative costs (66 percent, beginning in FY 1990) or the Federal government loses money. The $50 pass through provision enacted in 1984 also currently passes on to AFDC families $263 million a year which previously was returned to the Federal government. The Administration proposed to remove the protective floor on incentive payments in a step which would stimulate improved program performance while concurrently reducing federal deficits in the program.

Enforcement efficiencies mandated by the Child Support Enforcement Amendments of 1984 and the Family Support Act of 1988

would also help to achieve the levels of cost effectiveness necessary to reduce federal deficits. However, States have not taken full advantage of these tools. Audit penalties threaten the States with financial consequences unless they proceed to undertake the necessary steps which will provide both more effective child support services to America's children and reduce the Federal deficit in the program.

Question. Why should the States be allowed to profit from this program, while the Federal government absorbs growing losses?

(In Millions)

	FY 1988	FY 1989	FY 1990
Federal Loss	$ 413	$ 447	$ 481
State Gain	378	453	488
Net Gain	3	6	7

Answer. States profit from the program while the Federal government loses money because of the statutory construction of the Child Support Enforcement program. There needs to be a more equitable funding arrangement which encourages States to perform more cost effectively and rewards States that do. The incentive payments were established to encourage and reward State child support enforcement programs which perform in a cost-effective and efficient manner. However, the current incentive structure is overly generous, rewarding States regardless of what they spend to achieve collections. The legislation proposed in President Reagan's FY 1990 Budget would begin to redress this by discontinuing the practice of awarding incentive payments to States whose performance is clearly substandard.

CHILD SUPPORT ENFORCEMENT

Question. I understand that Richard Kusserow, the Inspector General of HHS, has been working with your office in performing a match of absent parents who are delinquent in paying child support. In this matching process Mr Kusserow matched the HHS payroll to the tax intercept records used by Treasury to withhold tax refunds to delinquent parents. How many HHS employees were found delinquent and what were the amounts?

Answer. The Inspector General's study identified 406 HHS employees who were delinquent in their child support obligation. This represented arrears of nearly $2 million.

Question. What action is being taken to obtain withholdings and what financial benefit will be received by the federal government?

Answer. OCSE provided State Child Support agencies a list of the identified HHS employees so States could initiate wage withholding in all appropriate cases. The number of cases provided to States was reduced from 406 to 368 to reflect deletions resulting from updates to federal income tax offset files which indicated that some of the individuals were no longer delinquent.

In response to OCSE tracking, the States have reported the following actions:

	CASES
1) Wage Withholding already in effect	128
2) Wage Withholding requested following match	103
3) No longer employed by HHS; new employer unknown	9
4) Wage Withholding not appropriate*	102
	342
Awaiting Status Report	26
Total	368

* No longer owe arrears, are out of State's jurisdiction, etc.

Question. Since this match appears to be successful how have you assisted Mr. Kusserow in extending this match to other Federal employees and to other delinquent parents?

Answer. OCSE has provided its updated 1987 and 1988 tax year data containing names, Social Security Numbers and the amount of debt accrued by the individuals identified for federal income tax refund offset by the States to the Inspector General (IG). The IG's office has used this information to match with National Personnel Record Center (OPM), Department of Defense (DOD), and Postal Service files to identify federal employees with child support arrears.

Question. At this time do you have any sort of an estimate of possible payments or withholdings that would result just from Federal employees?

Answer. The IG estimates that 1,400 of the 9 million Federal personnel matched from the activity just described may be subject to withholding which could result in collections amounting to $23 million annually. The estimate is based on raw data which has not been validated by the IG at this point.

Question. Do you feel that the recoveries will be higher from private employees?

Answer. OCSE has not done any analysis of the recoveries that could be obtained from private employees. Currently 36% of collections are derived from wage withholding. This has increased dramatically since 1985 when only 1% of collections reportedly came from wage withholding. The wage withholding provisions of the Family Support Act are being implemented by States and will begin to recover additional collections from delinquent parents who are employed, whether by government or the private sector.

SCHEDULE FOR JOBS IMPLEMENTATION

Question. Please provide for the record a schedule for implementing various phases of the JOBS program including the

child care aspects. When do you plan to put performance standards into effect to measure the success of the JOBS program?

Answer. States are permitted to implement approved JOBS and Supportive Services plans on the first day of any quarter, starting as early as July 1, 1989, but no later than October 1, 1990. Although submitted separately, both JOBS and Supportive Services plans must be submitted concurrently and implemented in the same quarter. States are required to implement the JOBS and Supportive Services provisions of the Family Support Act effective October 1, 1990 and have a statewide program by October 1, 1992.

The transitional child care provisions are effective April 1, 1990. A State IV-A agency must submit a Supportive Services plan for transitional child care 45 days before the April 1, 1990 effective date. Where the State agency has not previously submitted a Supportive Services plan because it has not implemented the JOBS program, its Supportive Services plan must contain only those sections related to transitional child care.

Implementation of performance standards depends on a number of factors -- completion of our study of effective methodologies, State implementation of JOBS, State implementation of the Unemployed Parent program, and so forth. The Family Support Act requires, in section 203(b), that performance standards be developed not later than October 1, 1993. The Department is statutorily required to then submit these proposed performance standards to Congress. Just as we did with the proposed regulations for the Family Support Act, we will move as expeditiously as possible to follow Congress' direction in this area.

CHILD SUPPORT ENFORCEMENT

Question. What is the current status of the Office of Child Support Enforcement's (OCSE's) national child support telecommunications network? Has there been a problem developing a request for proposal? When will a request for proposal be ready? What is the best estimate of when the system will be operational?

Answer. There are two essential components to the establishment of the national Child Support Enforcement Network (CSENET) -- developing a standard set of interstate case management transactions and data and procuring a telecommunications technology to transfer that data.

The development of standard data transaction formats specific to child support enforcement has been completed. FSA has convened a panel of State and Federal program experts to develop standard data transmission formats and data elements common to child support enforcement in order to facilitate the electronic interchange of data in a standard manner among independently organized State child support jurisdictions. By developing a common architecture for data interchange we ensure that the proprietary format adopted by one state is not imposed on another.

FSA is awaiting a response from the General Services Administration regarding our agency procurement request for a delegation of procurement authority (DPA) before we can proceed with the RFP. Another factor affecting the development of the RFP

for the network is that the 8A consulting firm FSA hired to assist in the functional requirements analysis, comparative cost analysis and the actual development of the Request for Proposal became insolvent prior to completion of the RFP deliverables. Since October we have worked with the Small Business Administration to cancel out the contract with the defunct firm and to establish a new contract. These issues are now very close to being resolved and we expect to have a new consultant on board sometime during May.

However, FSA has made progress consistent with the development of a combined telecommunications-ADP and services procurement of this complexity. Work has been completed on comparative cost analysis, requirements and needs analysis, traffic volume estimates, determination of tentative sites, acquisition planning document and the submission of an agency procurement request for a DPA to GSA.

Our best estimate is that sites will be prepared, all equipment installed, and the network operational within 18 months of the award of the contract, which is now expected to occur in the first quarter of FY 1990.

Question. The budget justification notes that imposition of property liens and routine reporting of child support debts to credit bureaus are effective techniques for improving child support collections. How much additional collections can be attributed to each technique, both now and if used by all states? What has OCSE done to promote use of these techniques?

Answer. Results are beginning to become apparent from OCSE initiatives to promote use of liens and routine credit bureau reporting. In Connecticut, the lien program proceeds for 1987 were $914,973, a 268% increase over the amount of child support collected by the use of liens during 1986. Maine filed 1,477 child support related liens and collected close to $1.3 million during fiscal year 1987. OCSE has urged States to aggressively use liens as an enforcement remedy.

Reporting child support debts to credit bureaus is also becoming the established routine in more and more States. At the end of 1988, 15 States had established systems to report debt information to the national consumer reporting network and 13 others were in the process of developing systems.

OCSE has promoted cooperative efforts among State Support enforcement agencies and credit bureaus to establish routine reporting systems. OCSE developed and distributed "A Guide About Child Support Enforcement" to credit grantors to explain the benefits of child support data in consumer credit records.

OCSE has set up several meetings with the five major credit bureaus and the State Child Support Administrators concerning credit reporting. Last year, OCSE held a workshop on credit reporting in conjunction with the National State Child Support Enforcement Administrators Conference. A session on routine credit bureau reporting was also provided at the FSA Systems Conference in July 1988. This session focused on child support

and credit bureau experiences and highlighted the potential collection results in operating a credit bureau reporting system.

Question. What is the status of access by the Federal Parent Locator Service to state wage and unemployment compensation claim data? Is there a national repository of information or must each state be dealt with individually? Is there an estimate of savings associated with this requirement?

Answer. As required by the Family Support Act, the Department of Health and Human Services and the Department of Labor entered into a Memorandum of Understanding on January 23, 1989, regarding FPLS access to State wage and unemployment information. There is no national repository of information, instead each State's Employment Security agency maintains its own files of wage and unemployment information.

To obtain access to this information, the FPLS must enter into a cooperative agreement with an "Agent State." The Agent State must do a sole source contract with the vendor who currently provides the data processing services for the existing network (Internet) used by State Employment Security Agencies. In addition, an agreement must be signed between each State Employment Security Agency and OCSE. A model agreement, drafted by OCSE, was shared with the members of the Interstate Conferences of Employment Security Agencies' Interstate Benefits Committee for their review and comments. Negotiations with individual States will begin soon. The Internet provision of the Family Support Act becomes effective in January, 1990.

At this time it is difficult to estimate the cost savings, because OCSE cannot conduct a pilot test until all agreements are in place. Furthermore, we do not know what the total costs to obtain the data will be until we have completed negotiations with the Agent State, the contractor, and all State Employment Security Agencies.

OFA'S FRAUD AND WASTE INITIATIVE

Question. Under the caption, "Management Savings" (p.22), FSA states that a planned initiative of the Office of Family Assistance (OFA) in fiscal year 1990 will be "to identify, correct and prevent waste and fraud." OFA's strategy includes encouraging states to implement "the optional fraud control program" and use administrative hearings for disqualification proceedings, and requires states to implement a pre-eligibility fraud prevention program. Could you describe for us this "optional fraud control program"? What has been your experience with this program thus far? Has it been successful in any states or localities, and if so, why is it only an "optional" rather than mandatory program for the states?

Answer. In accordance with section 9102 of the Omnibus Budget Reconciliation Act of 1987, Public Law 100-203, Congress provided an option to State agencies to implement a fraud control program which would disqualify intentional program violators from participation in the AFDC program. This optional program prescribes sanctions for individuals determined by a Federal or State court or administrative hearing to have committed an

intentional program violation(s) and authorizes funding at a 75 percent Federal reimbursement rate for costs incurred to carry out such a program. Many State agencies are in the process of implementing this program and it is premature to indicate its degree of success.

Question. Also, could you describe exactly what you mean by a pre-eligibility fraud prevention program? Is there any precedent for such a program? If so, where has it been used and how successful has it been in terms of its costs, resource requirements, and fraudulent benefit payments prevented? Why has such a program not been made optional for the states as you are doing with the previously discussed optional fraud control program?

Answer. A State-operated pre-eligibility fraud prevention program uses measures such as automated data matches outside of the Income Eligibility Verification System, home visits, collateral contacts, credit bureau inquiries to identify a fraudulent application prior to the establishment of eligibility.

Demonstration projects conducted in California (Orange and San Diego Counties) under section 1115 of the Social Security Act have been cited as the precedent for this program. According to the HHS Office of the Inspector General, these demonstrations were successful and cost effective.

This program is not optional for States because the Family Support Act of 1988 (Public Law 100-485) mandated that all States initiate pre-eligibility fraud detection measures as a means of preventing fraud in the AFDC program.

FRAUD AND WASTE PREVENTION

Question. A fraud and waste prevention component mentioned on p.22 of the budget justification is the proposing of additional incentive for reducing state and local administrative costs and error rates. Exactly what "incentives" do you have in mind here? Is this another term for some form of federal fiscal sanctions against states that have high error rates? Will these incentives result in additional costs to the federal government? If so, how much has been included in the 1990 budget for these costs?

Answer. The specific reference on p. 22 of the Congressional Justification states that FSA is "proposing additional incentives for reducing State and local administrative costs and error rates." The incentives proposed under President Reagan's FY 1990 Budget were to: (1) freeze FY 1990 funding for State and local administrative costs at FY 1989 levels less amounts for enhanced matching, providing an incentive for more efficient State operations; and, (2) provide incentive payments to States whose AFDC quality control error rates are below the error rate target of three percent. The amount of the incentive would equal half the difference between three percent and the State's actual error rate, times the Federal share of its total payments. Total incentives are expected to be approximately $1 million in FY 1990.

Question. Another component in preventing fraud and waste is the planned promotion, presumably among the States, of the integration into operations of innovative techniques, such as error-prone profiling, computer-matching, and pre-screening to prevent duplication and error. What are the privacy and due process implications of these techniques? Also in view of the recent enactment of the Computer Matching and Privacy Protection Act of 1988, what requirements will OFA and the states have to meet in using these techniques, such as establishing Data Integrity Boards, preparing cost/benefit estimates, and executing matching agreements?

Answer. The suggested pre-eligibility fraud techniques do not conflict with the existing privacy provisions contained in section 402(a)(9) of the Social Security Act and the Federal regulations at 45 CFR 205.50. These provisions limit the use or disclosure of information concerning applicants and recipients for purposes directly connected with the administration of the AFDC program under an approved Title IV-A State plan. With reference to the due process implication, applicants will continue to be afforded the opportunity for a fair hearing as a result of a denial in accordance with section 402(a)(4) of the Social Security Act and the Federal regulations at 45 CFR 205.10.

With respect to the Computer Matching and Privacy Protection Act of 1988, OFA is currently in the process of developing implementing regulations. A key provision of these regulations provides a notice time frame of 30 days to an individual before any adverse action can be imposed. This situation only applies to information generated by an automated matching program which has been independently verified by the State agency. This represents an expansion of current rules which require a State agency to provide a "timely" notice to an individual of at least 10 days before any adverse action can be taken. An additional safeguard is the requirement for conducting independent verifications of the computer produced information in order to confirm its accuracy. State agencies will be prohibited from taking adverse actions against an individual prior to completing this independent verification process.

JOBS PROGRAM

Question. The Administration is requesting approximately $350 million for the JOBS program in fiscal year 1990, a figure which includes transitional WIN funds. How did the Administration arrive at this estimate? How many States are expected to have switched to JOBS as of the beginning of fiscal year 1990 and by the mid-point of fiscal year 1990? Do the states expected to switch early on include such large states as California and Massachusetts, which currently invest large amounts of state funds in work/welfare programs?

Answer. The $350 million is our best estimate of actual program costs in FY 1990. The estimate was derived using national estimates of the percentage of caseload participation in the first year, JOBS activities unit costs, and many other related factors; it is not based on a state by state expectation of participation. Fifteen State have submitted State plans for implementing JOBS in July; They are: Arkansas, California,

Connecticut, Georgia, Iowa, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, Ohio, Oklahoma, Rhode Island, and Wisconsin. We do not know for certain how many States will switch at the beginning or mid-point of FY 1990. Should the requested amount be insufficient to fully implement the JOBS program, the Administration will seek a supplemental appropriation would be needed.

Question. The Family Support Act requires HHS to perform a number of functions in implementing the JOBS program. Please describe the status and/or your plans for completing each of the following: program regulations; performance standards; standard data collection and reporting requirements; and implementation study.

Answer. Program Regulations: the Family Support Act provided a statutory deadline of April 13, 1989 for publication of proposed rules implementing the JOBS program. The JOBS Notice of Proposed Rulemaking was submitted to the Federal Register for publication on April 13th and was printed in the Federal Register on Tuesday, April 18, 1989. In addition, the regulations developed with the Department of Labor (as required by the Statute) on JOBS working conditions were published on April 19th. The statute also requires that final rules be published by October 13, 1989. We are committed to meeting that deadline.

Performance Standards: before the Secretary can develop JOBS performance standards, information on operational JOBS programs must be collected and analyzed. The Assistant Secretaries for Planning and Evaluation and for Family Support will be consulting with other authorities at the Federal and State levels, as well as with other members of the research community, to develop a cost-effective plan for evaluating the JOBS program. Information needed to help develop performance standard will be a part of this larger evaluation. Later this fiscal year, we expect to let a contract to begin conducting the JOBS evaluation. We expect to meet the Family Support Act October 13, 1993 deadline for presenting a JOBS performance standards proposal to Congress.

Standard Data Collection: Until the final regulation is published and the sample system is approved, we will have an interim universe reporting system which will meet the requirements specified in sections 203(b) and 606 of the Family Support Act. In addition, we will be collecting information necessary to determine the State's participation rate and the percent of funds expended on target groups. We expect these reports to be in place by October 1, 1989 or January 1, 1990 depending on when the final regulation is published.

Implementation Study: We are not planning to conduct a discrete implementation study; instead, we will be collecting information about nationwide implementation of JOBS programs through our normal, ongoing administrative monitoring and approval processes. In addition, information about issues of program administration and operation will be obtained in the Process Evaluation componenent of our JOBS evaluation study.

NEW CHILD CARE PROGRAM

Question. Child care funded through the JOBS program must meet applicable state and/or local standards to ensure parental access to day care facilities. In the past, many work programs have not considered the quality of care purchased with program funds. What steps is HHS taking to ensure that child care in the JOBS program meets applicable requirements? In addition, what is HHS doing to ensure that states (a) have procedures to ensure that all center-based care meets health and safety requirements and (b) are developing guidelines for family day care?

Answer. No Federal financial participation will be available unless the States meet applicable State and or local standards for child care. In addition, the regulations propose that the State must have an assurance in the new State Supportive Service Plan that it: (a) has procedures to ensure that all center-based care meets health and safety requirements, and (b) is developing guidelines for family day care.

Question. The Family Support Act requires states to coordinate child care activities under JOBS with existing early childhood education programs such as Head Start. What is the Family Support Administration doing to increase coordination at the Federal level with those parts of HHS and other departments that administer early childhood education programs?

Answer. FSA secured input and comments from the Departments of Education and Labor, as well as other HHS components in preparing the proposed regulation. We have scheduled a formal coordination meeting with the Office of Human Development Services (Head Start), the Department of Education and the Department of Labor on May 5, 1989 to discuss planning and strategies.

AFDC ELIGIBILITY WORKERS

Question. Under the Family Support Act, it is likely that current AFDC workers will have numerous extra duties, such as forming agreements with recipients regarding the activities the recipient should undertake in the JOBS program, informing recipients of new changes in law (such as the child care provisions, the transitional benefits, and the AFDC-UP program), keeping track of the recipient's progress, and coordinating with other agencies. Are States planning to increase staff?

Answer. We believe that a number of State IV-A agencies will increase staff in order to comply with the provisions of the Family Support Act. This increase will most likely occur in those States that did not have an unemployed parent program prior to the Family Support Act.

Question. Will the persons called eligibility workers have to take on the added duties or will States hire social workers or employment counselors to perform these new responsibilities?

Answer. We believe that State IV-A agencies will have to increase the duties of current eligibility workers, possibly hire new staff or reassign staff from the pre-JOBS work programs.

Question. Are eligibility workers equipped with the training necessary to perform the duties expected under the new law?

Answer. State IV-A agencies have long established procedures for training staff on new statutory and legislative requirements. We are confident that adequate training will be provided.

Question. Will existing staff have enough time (or the morale) to adequately aid recipients?

Answer. We believe that existing State staff will continue to provide adequate service to recipients and be strongly motivated in carrying out the responsibilities of the Family Support Act given its objectives of maintaining family stability and assisting individuals achieve self sufficiency.

JOB CREATION PROJECTS

Question. Several members of the Senate have recommended full-funding of section 505 of the Family Support Act of 1988, which authorized $6.5 million for job creation demonstrations. How much is included in the President's budget for such demonstrations?

Answer. The Administration has not requested additional funds for demonstrations in FY 1990. We will use available research funds for FY 1990. It should also be noted that this demonstration is similar to a Community Services discretionary program. If Congress divides the residual in such a way as to continue the Community Services Block grant, this program would be duplicative.

The Family Support Act authorizes numerous studies, reports, and demonstrations. As is our normal practice, we will look carefully at each authorized use of funds in light of evaluation funds currently available in the Department. If additional resources are required after research and demonstration funds have been appropriated, then, after the funds have been appropriated, we will take this under consideration along with our view of the Family Support Administration's entire budget in light of negotiations with Congress on programs in the residual category.

Question. What similar programs are funded in other Federal agencies?

Answer. DHUD's Community Development Block Grant (CDBG), is a fairly unrestricted program which allocates $3 billion per year directly to cities to be distributed at the cities' discretion to local organizations, businesses and entities largely for economic development activities such as job training, construction, job creation, infrastructure improvements, and land acquisition. The proportion of funds spent on activities comparable to those in the Job Creation Demonstration is not known since HUD does not collect data at that level. However, about 13 percent of the funds are for loans and grants to businesses and about $19 million is used for economic development purposes.

The Department of Commerce operates an economic development grant program for public improvement and public works purposes. Job development and job creation are implicit. However, as with

HUD's CDBG, there are no requirements for creating jobs for welfare recipients or for other low-income people.

Question. How would this program differ from the Community Economic Development grants provided under the Community Services Block Grant appropriation?

Answer. Job Creation Demonstrations (JCD) under the Family Support Act duplicates Community Services Block grant programs from the perspective of what we can learn. From a policy perspective, differences are minimal. Similar demonstrations could be operated under Community Economic Development (CED) grants as well as with the Demonstration Partnership Program (DPP).

All three programs focus on projects to achieve increased self-sufficiency of low-income people though only the JCD gives emphasis to AFDC recipients. All three programs make funds available to nonprofit organizations though CEDs are restricted to community development corporations.

CEDs and JCDs focus on creating employment opportunities while DPPs also allow grantees to provide training to program participants. JCDs must provide technical assistance and financial assistance to private employers for this purpose while CEDs may directly operate businesses, involve construction projects, or give venture capital to employers when creating employment opportunities.

WEATHERIZATION

Question. To what extent are energy savings realized by weatherization assistance?

Answer. The Family Support Administration does not collect nor maintain information on the impact and cost benefit of weatherization.

The Weatherization Administration, Office of State and Local Programs of the U.S. Department of Energy published a study of the effects of weatherization based on a national sample in August, 1984 titled Weatherization Program Evaluation: A Service Report by Gerald E. Peabody. This publication is available from the Department of Energy.

Question. What impact have funding reductions had on the weatherization component?

Answer. Based on states' estimates obtained from HHS' LIHEAP telephone surveys, funds obligated for weatherization decreased $57 million from FY 1985 (the year of highest federal funding) to FY 1988. Also, the number of households receiving weatherization assistance decreased by 61,000 households from FY 1985 to FY 1988.

Question. For the past three years, what amount of funds have been provided under the Low Income Home Energy Assistance Program for weatherization and what percent of the total does that represent?

Answer. State estimates of funds obligated for weatherization/ other energy-related home repairs for fiscal years 1986 through 1988 indicate the following:

	Fiscal year		
	1986	1987	1988
Estimated amount (in millions)	$193	$220	$170
Percent of total[1]	9%	10%	9%

[1] Includes federal net allotments, carryover from previous fiscal year, oil overcharge funds, and state and other funds.

Question. Considering all funding available for weatherization (including Department of Energy and oil overcharge funds), what portion of households served have received adequate weatherization?

Answer. Under the Low Income Home Energy Assistance Act, states may spend up to 15 percent of their LIHEAP funds for "low-cost residential weatherization or other energy-related home repair for low-income households." States have varying definitions of "low-cost" and provide varying types of weatherization services. Different homes have widely varying needs for weatherization services. Under any definition, "low-cost" repairs cannot provide "adequate" weatherization to greatly substandard dwellings. Amounts spent per household vary considerably; maximum amounts spent per household under LIHEAP weatherization have varied state-by-state from about $500 to about $3,500. Beginning in FY 1982, states have weatherized between 157,000 and 483,000 homes each year with LIHEAP funds--over 1.8 million homes in all. Some states have returned to providing additional weatherization to homes partially weatherized in an earlier year.

States use Department of Energy Weatherization Assistance Program funds as well as LIHEAP funds for weatherization. Utility and other private sector programs also provide assistance with weatherization. In addition, in accordance with state priorities, states may spend oil overcharge funds under both the LIHEAP and DOE weatherization programs.

Because of the minimal reporting requirements under the LIHEAP block grant, we do not have data to provide a detailed accounting of LIHEAP weatherization services.

CHILD CARE UNDER THE JOBS PROGRAM

Question. The Family Support Act requires States to guarantee child care to the extent that such care is determined by the State agency to be necessary for an individual's participation in the JOBS program. States may provide child care directly or through contracts, vouchers, reimbursements, or cash. Do you have any indication of what method most States will use?

Answer. We have not polled the States to find out what methods they will use. It depends upon what methods are already in place within the State and how long it would take to put other payment methods in place. We understand that some States plan to expand their title XX systems, which already have many of these payment methods in place.

We have proposed that each State put in the State Supportive Service Plan what methods it will use for payment of child care services. We will have a better indication of the payment methods States will use when the State Supportive Service plans are submitted, prior to implementation.

Question. Do you know if any State will provide the child care directly?

Answer. We understand that one major metropolitan city is planning to provide short term child care on the JOBS program premises in order to have child care services available during short-term jobs search, assessment and orientation. Some States already involved in welfare reform demonstrations have indicated that lack of such child care has prevented many applicants and recipients from participating in such activities.

Question. What impact will this provision have on existing day care arrangements?

Answer. It is hoped that improved payment methods will encourage providers, who do not now want to provide services to low income clients because of slow reimbursement, to make child care services available to JOBS participants. It is also hoped that methods such as vouchers will encourage new family day care providers to become licensed or registered and eligible for reimbursement.

Question. What would the Federal government do if a State decided that it was not necessary for recipients with children over a certain age, 11 for example, to receive child care in order for them to participate in the JOBS program?

Answer. It is up to each State to determine when child care is necessary for an individual to participate in the JOBS program. In our proposed regulations, we limit Federal financial participation to those families with a dependent child under age 13 who requires such care.

STATE LEGALIZATION ASSISTANCE FUNDS

Question. The Immigration Reform and Control Act of 1986 appropriated $1 billion a year for fiscal years 1988 through 1991, and provided that unobligated funds were to remain available to the States through fiscal year 1994. The fiscal 1990 budget request proposed a reduction of $300 million, and indicates that a similar reduction will be requested for fiscal 1991 (p. 108).

Although the States may not need these funds now, how can you assume they won't need them by fiscal year 1994?

Answer. The Reagan Administration proposed reducing State Legalization Impact Assistance Grant (SLIAG) funding by $300 million in FY 1990 and FY 1991. Under the Bush Administration, SLIAG is part of the residual category, with specific funding levels to be determined through negotiations with Congress.

SLIAG is an interim program of assistance to State and local governments to ameliorate some of the financial impact resulting from the Federal decision to grant lawful resident status to aliens who had been living in the U.S. illegally. The legislative history indicates that among the primary reasons for establishing SLIAG were (1) the expectation that, upon legalization, aliens would have a "backlog" of public health needs that States would need help in meeting, and (2) the requirement in the Immigration Reform and Control Act (IRCA) that aliens granted lawful status under section 245A of IRCA (but not special agricultural workers -- SAWs) must meet English language and citizenship requirements between November 1989 and November 1990 in order to remain in legal status. This requirement created a substantial need for additional English language and citizenship instruction. State cost estimates for FY 1988 and FY 1989 largely account for both of these needs.

At this point, we still do not have complete actual cost information from States. However, State projections for FY 1988 and FY 1989 indicate that the $1.5 billion already made available to States for those years is adequate to cover most costs State and local governments will incur through FY94 as a result of the legalization program. The legislative history makes clear that Congress did not intend to meet 100 percent of costs that States might incur as a result of the legalization process. Furthermore, in implementing SLIAG, it has become clear that States already have been providing many public health, public assistance and education services to this group of aliens because lawful resident status is not a condition of eligibility for accessing many State and local programs. Thus, State and local government costs resulting from IRCA will not be as high as might have been thought.

Additionally, early data indicates that most legalized aliens are employed and do not rely on public services. Aliens were not eligible for legalization if they were likely to become "public charges," and early data shows low unemployment. This means that legalized aliens are taxpayers, contributing directly and indirectly, through their employers and their landlords, to State and local revenues.

Question. What is your position on the Kennedy/Kasten bill which would shift $200 million in previously appropriated, but unspent, Immigration Act funds for immediate refugee needs?

(Background: The Kennedy-Kasten bill, introduced in February 1989, has been referred to the Appropriations Committee. It would add $50 million for refugee resettlement costs under the jurisdiction of the Labor-HHS Subcommittee, and $150 million for State Department refugee processing costs under the Commerce-State-Justice Subcommittee.)

Answer. We oppose this proposal because we believe any additional refugee needs can be funded within existing funding levels.

OIL OVERCHARGE FUNDS FY 89 & 90

Question. How much money do you estimate will be distributed to the States for use in FY 1989 and FY 1990? Please provide the basis for your estimate.

Answer. Based on our communications with DOE, approximately $350 million will be distributed to the States in FY 1989. This amount includes $127.3 million so far distributed in FY 1989. The $127 million, all Stripper Well funds, includes:

- o $12.9 million - first distribution of Texaco funds on 11/3/88
- o $81.0 million - Getty funds (on 4/6/89)
- o $33.4 million - other Stripper Well funds

Approximately $90 million in additional Texaco funds are expected in FY 1989. Based on the above information, we know of approximately $218 million and expect about $132 million more in FY 1989, most likely from Stripper Well settlements.

Under terms of the settlement reached last year, Texaco agreed to pay $1.25 billion to DOE over a 6 year period, beginning in FY 1989. This timetable will result in a second payment to DOE of $190 million, plus accrued interest, in FY 1990. Beginning one year thereafter, Texaco will make four equal annual installments of $165 million, plus accrued interest. Presumably, each one of these payments will be reduced by 20% to be withheld by the Office of Hearings and Appeals (OHA) for a claims procedure, before being split evenly between the Federal and State governments. States, if they so choose, will be able to apply their share of the funds toward their LIHEAP programs.

Based on the Texaco formula, States can expect to see approximately $350 million as their share of this settlement from FY 1990 through FY 1994.

The Department of Health and Human Services does not control and cannot predict the date of actual distribution of additional oil overcharge funds. The Department of Energy is the source for information and estimates regarding the amount and distribution schedule of future settlements. The $350 million that States are expected to receive in FY 1989 represents monies from Texaco, DOE's Deposit Funds Escrow account, and several court escrow accounts. It should be noted that this amount is an estimation and could vary since these funds are generated by court orders and voluntary settlements, which are not controlled by either DOE or HHS.

Question. Of the funds expected to be available for FY 1989 and FY 1990, please provide (from DOE or otherwise) a listing of specific cases settled or expected to be settled (or otherwise

litigated) and the amount each is expected to yield (in total and the State's share of that total).

Answer. The Department of Health and Human Services is unable to provide a listing of specific oil overcharge cases currently in litigation. The Economic Regulatory Administration (ERA) in the Department of Energy is the source for information on pending settlements. ERA regularly provides Congress with reports on the amount of overcharges it expects to collect.

According to a recent General Accounting Office (GAO) report, Energy Regulation: The Quality of DOE's Oil Overcharge Information (March 1989; GAO/RCED-89-104), ERA reported 218 active oil overcharge cases were in administrative and judicial litigation, as of July 1988.

Question. According to HHS, $700 million is still available for use in LIHEAP. Does this figure include funds about which States have already adopted final State spending plans, either through the required legislative or executive process?

Answer. The $670 million in undesignated funds is based on what States have reported to DOE on their planned use of oil overcharge monies. The legislature and/or governor in each State would have approved a plan to allocate oil overcharge funds for specified programs before submitting that plan to DOE for its approval (prior DOE approval is required before a State can expend Stripper Well funds).

Question. Can you provide us information about how much [oil overcharge] money has been reallocated by the States (i.e., spending plans changed after initial adoption) in the past two years, so that we can estimate how much of the currently allocated funds might be reallocated? Also, of the reallocated funds, how much went to LIHEAP?

Answer. We cannot provide specific information on the amount of oil overcharge funds reallocated by the States. The States submit their plan to DOE and identify any reallocation of funds in those plans.

Detailed information about State plans and the types of projects submitted for approval under Stripper Well is available from DOE's Office of State and Local Assistance Programs, Energy Management Programs.

Question. How much Exxon and Stripper Well money have the States used for LIHEAP from FY 1986 through FY 1989?

Answer. In LIHEAP telephone surveys, the States have reported using $370 million in Exxon and Stripper Well funds for LIHEAP from FY 1986 through FY 1988. States have reported to DOE that they have designated about $400 million in Exxon and Stripper Well funds for LIHEAP, as of April 6, 1989.

Attached is a State chart detailing the known expenditures of oil overcharge funds for LIHEAP from FY 1986 through FY 1988. This information is based on estimates collected as part of HHS'

voluntary winter and summer telephone surveys of the States. We are currently collecting data from States for FY 1989.

Preliminary findings in our current survey for FY 1989 have indicated that some States erroneously double-counted oil overcharge figures, resulting in inflated estimates of LIHEAP uses of these funds. We are now seeking to correct these discrepancies before releasing the FY 1989 data.

Total oil overcharge funds used in LIHEAP
Exxon/Stripper Well yearly totals, fiscal years 1986-1988
Source: Office of Energy Assistance/ACF/HHS/DHS

	Exxon FY 1986	Stripper Well FY 1986	Total FY 1986	Exxon FY 1987	Stripper Well FY 1987	Total FY 1987	Exxon FY 1988	Stripper Well FY 1988	Total FY 1988	Total Oil Overcharge FY 1986-1988
Total	$24,139,832	$480,000	$24,619,832	$160,491,765	$25,199,750	$185,691,515	$134,189,268	$39,149,333	$173,338,601	$383,649,948
Alabama	$1,389,405	$0	$1,389,405	$0	$2,770,000	$2,770,000	$0	$0	$0	$4,159,405
Alaska	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Arizona	$0	$0	$0	$0	$0	$0	$400,000	$0	$400,000	$400,000
Arkansas	$480,000	$480,000	$960,000	$3,000,000	$0	$3,000,000	$1,000,000	$0	$1,000,000	$4,960,000
California	$0	$0	$0	$11,000,000	$10,000,000	$21,000,000	$7,000,000	$5,500,000	$14,500,000	$35,500,000
Colorado	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Connecticut	$3,300,000	$0	$3,300,000	$7,300,000	$0	$7,300,000	$6,300,000	$0	$6,300,000	$16,900,000
Delaware	$0	$0	$0	$0	$0	$0	$794,827	$0	$794,827	$794,827
Dist. of Col.	$794,906	$0	$794,906	$0	$0	$0	$0	$0	$0	$794,906
Florida	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Georgia	$7,000,000	$0	$7,000,000	$9,000,000	$0	$9,000,000	$6,336,796	$6,605,100	$6,940,796	$22,940,796
Hawaii	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Idaho	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Illinois	$0	$0	$0	$0	$11,300,000	$11,300,000	$0	$0	$0	$11,300,000
Indiana	$5,636,900	$0	$5,636,900	$6,194,942	$0	$6,194,942	$9,001,020	$0	$9,001,020	$20,943,000
Iowa	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Kansas	$0	$0	$0	$2,220,307	$0	$2,220,307	$4,934,343	$0	$4,934,343	$7,006,760
Kentucky	$0	$0	$0	$0	$0	$0	$430,145	$910,220	$1,444,000	$1,444,000
Louisiana	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Maine	$0	$0	$0	$200,000	$0	$200,000	$91,263	$0	$91,263	$291,263
Maryland	$0	$0	$0	$4,300,000	$1,091,750	$5,391,750	$460,531	$4,460,531	$4,772,143	$10,091,893
Massachusetts	$0	$0	$0	$5,050,000	$0	$5,050,000	$4,000,000	$7,000,000	$11,000,000	$16,050,000
Michigan	$0	$0	$0	$10,000,000	$0	$10,000,000	$9,900,000	$7,200,000	$17,100,000	$27,100,000
Minnesota	$0	$0	$0	$5,500,000	$0	$5,500,000	$0	$0	$0	$5,500,000
Mississippi	$0	$0	$0	$992,000	$0	$992,000	$1,900,000	$0	$1,900,000	$2,892,000
Missouri	$0	$0	$0	$3,100,000	$0	$3,100,000	$0	$0	$0	$3,100,000
Montana	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Nebraska	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Nevada	$232,454	$0	$232,454	$926,000	$0	$926,000	$900,000	$385,000	$400,000	$1,332,454
New Hampshire	$0	$0	$0	$240,000	$0	$240,000	$265,760	$0	$265,760	$505,760
New Jersey	$0	$0	$0	$0	$0	$0	$10,000,000	$0	$10,000,000	$10,000,000
New Mexico	$0	$0	$0	$2,250,000	$0	$2,250,000	$0	$0	$0	$2,250,000
New York	$0	$0	$0	$14,300,000	$0	$14,300,000	$0	$0	$0	$14,300,000
North Carolina	$0	$0	$0	$640,000	$0	$640,000	$3,000,000	$0	$3,000,000	$3,640,000
North Dakota	$0	$0	$0	$0	$0	$0	$1,397,434	$0	$1,397,434	$1,397,434
Ohio	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Oklahoma	$0	$0	$0	$4,232,702	$400,000	$4,632,702	$1,000,000	$0	$1,000,000	$5,632,702
Oregon	$0	$0	$0	$2,104,226	$0	$2,104,226	$0	$0	$0	$2,104,226
Pennsylvania	$0	$0	$0	$30,000,000	$0	$30,000,000	$40,970,000	$0	$40,970,000	$70,970,000
Rhode Island	$0	$0	$0	$150,000	$0	$150,000	$0	$2,000,000	$2,050,000	$2,200,000
South Carolina	$0	$0	$0	$5,097,402	$0	$5,097,402	$2,300,000	$0	$2,300,000	$7,397,402
South Dakota	$0	$0	$0	$0	$0	$0	$1,272,771	$0	$1,272,771	$1,272,771
Tennessee	$1,000,000	$0	$1,000,000	$1,000,000	$0	$1,000,000	$3,300,000	$0	$3,300,000	$5,300,000
Texas	$0	$0	$0	$0	$0	$0	$900,000	$1,750,000	$2,250,000	$2,250,000
Utah	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Vermont	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Virginia	$0	$0	$0	$1,340,000	$0	$1,340,000	$6,150,000	$0	$6,150,000	$7,550,000
Washington	$0	$0	$0	$1,000,000	$0	$1,000,000	$0	$420,002	$420,002	$1,420,002
West Virginia	$0	$0	$0	$2,000,000	$0	$2,000,000	$3,000,000	$0	$3,000,000	$5,000,000
Wisconsin	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Wyoming	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0

NOTE: FY 1988 total for Kentucky includes $33,436 in interest from Stripper Well funds and $199 in interest from Exxon funds.

4/3/89 OEA/ec/ASP-FY.WQ1

USE OF OIL OVERCHARGE FUNDS FOR LIHEAP

Question. What percentage of the total Exxon and Stripper Well funds included in the States' final spending plans (or allocations) is going to LIHEAP?

Answer. The Department of Energy, not HHS, monitors the distribution and obligation of oil overcharge funds by the States. Based on the most recent information from DOE, we have been informed that proposals involving $1,702,857,379 of Exxon funds have been designated by States for either LIHEAP or the four DOE programs. Of that $1.7 billion, DOE indicates that $320,182,215 of Exxon funds are designated for LIHEAP, or 19 percent.

For Stripper Well funds, DOE indicates that States have submitted proposals totaling $847,360,527. Not all of these proposals have been approved, and some have actually been rejected. Of the $842 million in approved plans, about $81 million has been earmarked for LIHEAP, just less than 10 percent. Stripper Well funds have fewer restrictions on use than Exxon funds. We expect that States will review their use of overcharge funds according to a combination of Federal appropriations and what they perceive as the primary needs in their states.

Question. How many other programs can these funds be spent through?

Answer. U.S. v. Exxon Corporation 561 F. Supp 816 (D.D.C. 1983) provides that the $2.1 billion judgement should be distributed by the States and territories through the following Federal programs:

- Low Income Home Energy Assistance Program (LIHEAP) which is administered by the Department of Health and Human Services. A State may use LIHEAP funds for heating, cooling, crisis, or for weatherization activities.

- Low Income Weatherization Assistance Program (LIWAP) which is administered by the Department of Energy. WAP funds are used exclusively for weatherization activities.

- Institutional Conservation Program (ICP) is administered by the Department of Energy. The ICP program requires a match of State and local funds to identify energy conservation needs for and to weatherize public and private, non-profit schools and hospitals.

- State Energy Conservation Program (SECP) is administered by the Department of Energy. SECP supports state energy conservation planning and development and implementation of State energy conservation programs.

- Energy Extension Service (EES) is administered by the Department of Energy. EES serves small-scale energy users through technical assistance, disseminating information and demonstrating energy conservation techniques.

The Stripper Well settlement agreement, M.D.L. No. 378, with $1.1 billion distributed so far, cites these five Federal energy conservation programs as well. In addition, Stripper Well permits States and territories to distribute oil overcharge funds through uses approved by the Department of Energy's Office of Hearings and Appeals in Subpart V refund proceeding, and those referenced in the consent order which DOE entered into in 1981 with Standard Oil Company of California (Chevron) on October 26, 1981. Some states are allocating a large portion of stripper well funds for roads bridges and similar infrastructure projects.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

LOW INCOME ENERGY ASSISTANCE

Question. In fiscal year 1989, Pennsylvania reported shortening the program year, reducing the income eligibility levels for the program from 150% to 135% of poverty (26,000 households) and authorizing $31 million from the oil overcharge fund to address the reduction in the state's allocation. How many low income households does the Department estimate will be eliminated from the program in fiscal year 1989?

Answer. Because LIHEAP is a block grant which affords the grantees flexibility in designing their energy assistance programs, there is no precise correlation between changes in federal appropriations and households served. Like other states, Pennsylvania may supplement its federal appropriation with State or oil overcharge monies, not exercise its option to transfer funds out of LIHEAP into other block grants, reduce a service component such as cooling or weatherization or reduce the size of the benefit provided, or focus on lower income families.

Based on preliminary estimates from the FY 1989 winter LIHEAP telephone survey, it appears about 2 percent fewer households will receive heating assistance in FY 1989. The Department will have a more accurate picture after the FY 1989 summer LIHEAP telephone survey is completed.

Question. The President's FY '90 budget proposes to reduce funding for the Low Income Home Energy Assistance Program by $283 million below the fiscal year 1989 appropriation. The National Consumer Law Center, commissioned by the Department of Energy to investigate the status of oil overcharge allocation decisions, indicates that 95.4% of the funds have been allocated by the states. Does the Department continue to believe that significant reduction in the number of households served and the average benefit level can be avoided through the states' use of "other resources" for the Low Income Home Energy Assistance Program?

Answer. The President's proposed FY 1990 Budget request did not just look at the availability of oil overcharge funds. It also considered the increasing affordability for energy and the energy benefits available in other Federal programs.

Residential energy costs peaked in 1984. By 1988, the current dollar low income weighted home energy expenditures were down by 9 percent because of fuel price reductions. In 1985, LIHEAP eligible households paid 5.4% of income for heat. In 1988, LIHEAP eligible households paid 3.9% of income for heat, for a reduction of 34%. This increasing affordability has saved LIHEAP eligible households substantial amounts of money.

The Federal government considers the energy needs of low income households in other income maintenance programs. The Consumer Price Index (CPI)--the inflation factor used for indexing programs such as Social Security and Supplemental Security Income is based in part on fuel prices. The Department of Housing and Urban Development will provide housing and

assistance with utility costs to 4.4 million households in 1989. Federally matched funds are available from Emergency Assistance funds to those states that wish to provide heating supplements to the 3.8 million households receiving AFDC. Food Stamp households can deduct a portion of their housing and utility costs from income thereby increasing their food stamp allowance by about $30 per month. In addition, LIHEAP benefits are not counted as income in calculating food stamp benefits.

Question. How much does the Department estimate the States will receive in each of fiscal years 1989 and 1990 in newly released oil overcharge funds?

Answer. Based on our communications with DOE, approximately $350 million will be distributed to the States in FY 1989. This amount includes $127.3 million so far distributed in FY 1989. The $127 million, all Stripper Well funds, includes:

- o $12.9 million - first distribution of Texaco funds on 11/3/88
- o $81.0 million - Getty funds (on 4/6/89)
- o $33.4 million - other Stripper Well funds

Approximately $90 million in additional Texaco funds are expected in FY 1989. Based on the above information, we know of approximately $218 million and expect about $132 million more in FY 1989, most likely from Stripper Well settlements.

Under terms of the settlement reached last year, Texaco agreed to pay $1.25 billion to DOE over a 6 year period, beginning in FY 1989. This timetable will result in a second payment to DOE of $190 million, plus accrued interest, in FY 1990. Beginning one year thereafter, Texaco will make four equal annual installments of $165 million, plus accrued interest. Presumably, each one of these payments will be reduced by 20% to be withheld by the Office of Hearings and Appeals (OHA) for a claims procedure, before being split evenly between the Federal and State governments. States, if they so choose, will be able to apply their share of the funds toward their LIHEAP programs.

Based on the Texaco formula, States can expect to see approximately $350 million as their share of this settlement from FY 1990 through FY 1994.

The Department of Health and Human Services does not control and cannot predict the date of actual distribution of additional oil overcharge funds. The Department of Energy is the source for information and estimates regarding the amount and distribution schedule of future settlements. The $350 million that States are expected to receive in FY 1989 represents monies from Texaco, DOE's Deposit Funds Escrow account, and several court escrow accounts. It should be noted that this amount is an estimation and could vary since these funds are generated by court orders and voluntary settlements, which are not controlled by either DOE or HHS.

LIHEAP

Question: Does the Department continue to project stable energy prices for fiscal year 1990? How do the estimates for energy costs compare with those for each of the three previous fiscal years?

Answer: The percent of income for heating expenditures of low income households has gone from 5.4% of annual income in 1985 to 3.9% in 1988 for a reduction of 34%. The estimated percent of income expended for heat by LIHEAP recipient households has dropped from 6.6% in 1985 to 5.4% in 1988 a reduction of 18%.

Energy prices are now stable in that the price variations from year to year are within a manageable range. From 1979 to 1984, residential fuel prices were rising from 10% to 35% each year. From 1985 to 1989 fuel price variations up and down have been limited to 1-10% per year. According to DOE's base case estimate, the rise in residential fuel prices over the next year will be 2.96% of natural gas, 6.65% for fuel oil, and 3.66% for electricity.

Over 55% of low income households and LIHEAP recipient households heat with natural gas. The latest projection from DOE (January, 1989) indicates a 4.4% drop in natural gas prices from 1986 to 1989 and projects a 3% rise in natural gas prices between 1989 and 1990.

Bulk fuels such as kerosene and liquified petroleum gas (LPG) will track with residential fuel oil prices. Less than a quarter of low income households use petroleum based fuels for heating.

Given the Department of Energy's projections for price changes in the types of fuel used by low income households for heat, constant dollar prices of fuel should remain steady between 1989 and 1990.

Question. What impact on the demand for LIHEAP services has the heat waves of the last several summers had on LIHEAP's cooling assistance program? Have federal funding cuts led to a reduction of households receiving cooling assistance during the past five years?

Answer. HHS cannot statistically determine the demand for LIHEAP services as states are not required to report on the number of households applying for cooling assistance. On the other hand, the number of states providing cooling assistance may provide a rough index of the demand for cooling assistance. As indicated below, the number of states providing cooling assistance has remained fairly stable whereas the number of states providing summer crisis assistance has fluctuated more from FY 1984 through FY 1988:

Fiscal year	Number of states providing Cooling assistance[1]	Summer crisis assistance[2]
1984	11	8
1985	10	6
1986	12	12
1987	12	8
1988	11	11

As indicated below, state-reported data on the number of households receiving cooling assistance indicate a downward trend for fiscal years 1987 and 1988. The number of households receiving summer crisis assistance was lowest in FY 1984, peaked in FY 1986, and declined somewhat in FY 1987 and FY 1988.

Fiscal year	Number of households assisted Cooling assistance[1]	Summer crisis assistance[2]
1984	538,000	29,000
1985	511,000	Not available
1986	536,000	114,000
1987	366,721	61,000
1988	309,000	58,000

[1]Excludes three states that provide combined heating and cooling assistance benefits.
[2]Excludes states that provide year-round crisis assistance.

COMMUNITY SERVICES BLOCK GRANT

Question. While President Bush's proposal to fully fund the McKinney Homeless Assistance Act programs includes $42 million for Community Services to the Homeless, it is not clear whether funding for the Community Services Block Grant is included. Does the Bush budget restore funding for the basic block grant?

Answer. In the Bush Budget, programs authorized by the Community Services Block Grant Act could be funded out of the "residual" category. Recognizing the importance of the homeless initiatives authorized by the Steward B. McKinney Homeless Assistance Act, the Administration is submitting a budget amendment to fully fund the Emergency Community Services Homeless Grant Program (or EHP). Since the EHP authorization is separate from the CSBG Act, full funding for EHP is separable from CSGB funding.

Even if budget negotiations resulted in reduced CSBG funding, the effect on community action agencies (CAAs) should be modest. The precursor to the CSBG helped community action agencies (CAAs) get started. CAAs now administer many programs, including many Federal programs. As a result of their success, CAAs depend on the CSBG for about 12% of their resources. Now, the CSBG pays for additional administrative overhead that might otherwise be allocated to specific programs (perhaps 40% of the CSBG) and services for which States have not provided Social Services Block Grant funds. In addition, over $40 million in FY 1989 CSBG appropriations were earmarked for direct Federal grants that do not fund these services by CAAs. By including the CSBG in the residual category, the Administration has indicated its readiness to discuss with Congress the avenues through which Federal funds are given to CAAs.

Question. If not, how will the Community Action Agencies have sufficient resources to carry out the responsibilities of the Homeless Block Grant if funding from the Basic Block Grant is eliminated?

Answer. Community Services Block Grant (CSBG) funds are issued to the States to support social services activities for the poor conducted by 1070 community-based organizations, including a network of 861 community action agencies (CAAs), formerly funded by the Community Services Administration and earlier by the Office of Economic Opportunity. These CAAs are nonprofit organizations that receive, on average, only about 12 percent of their funding from CSBG. Other funds are provided by other Federal programs. State or local governments, or the private sector. CSBG funds were never intended to be their sole source of support.

In addition, the Emergency Community Services Homeless Grant Program (EHP) funds may be used to support administrative expenses at the CAA level (but not at the State level) for homeless activities. Also, President Bush has requested full funding of $42 million for FY 1990 for the Emergency Community Services Homeless Grant Program (EHP) in the Office of Human Development Services.

Question. With cities such as Philadelphia struggling to address the problems of the homeless and to provide services to more low-income individuals, how can the elimination the Community Services Block Grant be justified?

Answer. Without the CSBG, CAAs would still receive substantial amounts of Federal funds. These locally created entities administer numerous programs funded by other Federal, State and private agencies/organizations most of which receive administrative funds for their operations. In addition, President Bush has requested full funding of $42 million for FY 1990 for the Emergency Community Services Homeless Grant Program (EHP) in the Office of Human Development Services.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

REFUGEE AND ENTRANT ASSISTANCE

Question. The budget request for FY 90 proposes to cut funding for State Administered Programs by $95.1 million, a cut of nearly 30%. Has a corresponding 30% reduction occurred in the eligible refugee population? If not, how does the estimated time eligible refugee population in FY 90 compare with FY 89?

Answer. Based on the present FY 1989 refugee admissions ceiling of 90,000 (exclusive of the up to 4,000 admissions available for entirely private-sector sponsorship) and the 84,000 refugee admissions projected for FY 1990 in the proposed budgets of both HHS and the Department of State, we estimate that the time-eligible population will decrease from a 24-month population of approximately 152,000 refugees in FY 1989 to a 15-month

population of approximately 109,00 in FY 1990 -- a reduction of 28%.

Question. On August 24, 1988, the Department issued a final regulation reducing the eligibility period for refugee cash assistance (RCA) and refugee medical assistance (RMA) from 18 months to 12 months. It was my understanding that beginning in the 13th month, states subsequently were eligible to receive reimbursements for GA and GMA up through the 24th month. However, the Department's budget justification for FY 90 indicates that states will be reimbursed fully for GA and GMA only from the 13th through the 15th month. Is this a change from FY 89?

Answer. Yes. The FY 1990 Reagan budget request proposed that funding for cash and medical assistance be limited to the first 15 months after a refugee's date of arrival in the United States. This would include: 15 months for AFDC, SSI, and Medicaid; 12 months for RCA and RMA; and a refugee's months 13-15 in the U.S. for GA and GMA after the RCA/RMA eligibility period has expired.

Question. Has the Department issued regulations limiting the period for GA and GMA reimbursement from 12 to 3 months?

Answer. No. The overall reimbursement period is dependent entirely on the availability of funds. The Reagan budget request was based on the funds estimated to be necessary for an overall 15-month reimbursement period.

Question. What states do not have a General Assistance program? How many refugees does the Department estimate lost Federal or state support as a result of the August 24th regulations?

Answer. Most, but not all, States have some form of State or local General Assistance program. However, the nature, extent of eligibility, and types and duration of benefits vary greatly. In some States, these programs vary by county or city. A recent study has not been done.

The reduction in the RCA program from 18 to 12 months, which was announced by the regulation published August 24, went into effect October 1, 1988. This regulatory change advanced by 6 months (from a refugee's 18th month in the U.S. to the 12th month) the point in time after which refugees who had been receiving RCA would have to rely on the regular GA/GMA programs available in their locality of residence rather than on the special transitional eligibility provided by the RCA/RMA programs.

We estimate that approximately 1,000 RCA recipients lost their time-eligibility as a result of the regulation.

Question. How much would it cost in FY 90 to extend GA and GMA eligibility for months 16 through 24?

Answer. It would cost an estimated $8.8 million in additional funding in FY 1990 in order to extend GA and GMA eligibility for months 16 through 24.

Question. How much above the President's request would it cost to increase RCA and RMA Eligibility from 12 to 18 months?

Answer. It would cost an estimated $35.3 million in additional funding in FY 1990 in order to extend GA and GMA eligibility for months 12 to 18 months.

Question. The President's budget also proposes to reduce refugee categorical assistance from 24 to 15 months in FY 90. Have regulations been proposed to reduce the eligibility period?

Answer. No. The overall period of Federal refugee funding for cash and medical assistance is dependent on the amount of funds available rather than on regulations. The amount requested for FY 1990 is estimated to be sufficient for 15 months, given the assumptions in the budget request regarding refugee arrivals in FY 1989 and 1990.

Question. Has the Department consulted with the appropriate committees of jurisdiction in the House and the Senate concerning the propriety of reducing further the periods for eligibility?

Answer. This is a budget and appropriations issue, we believe our testimony here today represents the appropriate Congressional consultation. The reduction requests in the Reagan Budget are fully allowable under the authorization statute.

Question. What evidence does the Department have to support the contention that a reduction in eligibility periods yields a reduction in refugee dependency rates?

Answer. The reduction in the funding period from 24 to 15 months would not affect the eligibility of refugees for assistance since their eligibility for AFDC, SSI, Medicaid, GA, and GMA exists independently of the availability of Federal refugee funds.

Since a larger percentage of refugees tend to need assistance during their early months in the U.S., we would not expect a 15-month funding period to result in a lower average dependency rate than would a 24 month funding period. (We use the term "dependency rate" to refer to the percent obtained by dividing the number of recipients by the time-eligible population -- in the case of the Reagan proposal, the population of refugees who have been in the U.S. less than 15 months.) However, we believe that reducing the period of 100% Federal reimbursement of State costs will encourage states to more quickly reduce welfare dependency.

Question. Recently, the refugee admissions ceiling for 1989 was raised from 94,000 to 116,500. This appears to represent a 24% increase over the base on which the domestic resettlement budget was built. Does the Department intend to request additional funds in FY 89 for Domestic Refugee Programs?

Answer. If a final decision is made to increase the FY 1989 ceiling by this amount, the Department intends to propose that $21.9 million in already appropriated funds be reprogrammed from the State-administered cash and medical assistance program to the voluntary agency matching grant program.

Question. Was a request for supplemental funds made to the Office of Management and Budget?

Answer. Yes. A request was made for supplemental funds to the Office of Management and Budget.

Question. Did the Office of Refugee Resettlement make a request to the Department for supplemental funding?

Answer. Yes. The Office of Refugee Resettlement did make a request to the Department for supplemental funding.

Question. What impact will the additional 22,500 refugees have on the FY 90 budget request?

Answer. We estimate that the additional cost in FY 1990, under the proposed Reagan budget policy of 15 months' funding for cash and medical assistance, would be $16.4 million.

Question. On February 13, 1989, I joined with my colleagues from Oregon in sending a letter to the Director of the Office of Refugee Resettlement expressing dismay over a regulation proposed on January 25, 1989 concerning the Department's method for calculating Targeted Assistance grants. To date we have not received a response. When can we expect to receive a response?

Answer. The comments we received are being carefully considered, and we expect to reach a decision shortly.

Question. Has the comment period on the regulations expired?

Answer. Yes. The comment period has expired.

Question. How many comments have been received?

Answer. Approximately 125 comments have been received.

Question. What has the tenor of the comments been to date?

Answer. In general, the proposal was opposed by commenters from counties which would have received smaller allocations of funds than under the old formula and was supported by commenters from counties which would have received larger allocations.

Question. Does the Department plan to move ahead with final regulations in FY 89?

Answer. Yes. We plan to publish a final notice of targeted assistance allocations as soon as the review of comments has been completed and a decision reached since it is necessary

to issue such a notice in order to provide a basis for awarding the FY 1989 targeted assistance funds.

Question. What justification is there for altering the TA formula well into the current fiscal year and well after states have made plans under the existing formula?

Answer. The formula which has been used to date has been based on the impact of arrivals during FY 1980-1982. The Department believes it is no longer appropriate to make limited funds available solely on the basis of the needs of refugees who arrived so long ago. Many years have passed since the program was initiated, and to date the impact of subsequent arrivals has not been taken into account in the allocation formula.

Question. How does the Department plan to pay for the program costs associated with the increase in admissions in FY 89? How many of the additional 22,000 refugees does the Department estimate will seek services in FY 89?

Answer. As indicated previously, we intend to propose that funds be reprogrammed to the voluntary agency matching grant program for this purpose. We estimate that all of these new refugees would seek and receive assistance and/or services through the voluntary agencies during their initial period in this country.

Question. The budget justification indicates that the Department plans to publish a series of regulations concerning the Social Services program. Have regulations been issued? If not, does the Department still intend to issue these regulations? What changes in the program would be made by the regulations?

Answer. These references in the budget justification were prepared before the issuance of final regulations on refugee social services and other aspects of the refugee program which were published in the Federal Register of February 3, 1989 (54 FR 5463). As published, the regulations do not limit eligibility to receive social services to those refugees who have been in the U.S. less than 36 months.

COMMUNITY SERVICES PROGRAMS

Question. President Reagan's budget proposed the elimination of funding for the Community Services Block Grant Program. Does President Bush concur in the recommendation that these programs be eliminated?

Answer. The President has included the CSBG program in the residual category which will be addressed by the Administration and the Congress this session.

Question. The President has requested full funding for McKinney Act Programs. Does this include a restoration of funding for the Community Services Homeless Program?

Answer. Yes. President Bush as requested full funding for the Emergency Community Services Homeless Grant Program (EHP) in

the Office of Human Development Services for fiscal year 1990, which would amount to $42 million.

Question. If Funding for the basic Block Grant is eliminated, and the core support is lost, will the Community Action Agencies be able to carry out their responsibilities under the Block Grant for the Homeless?

Answer. Without the CSBG, CAAs would still receive substantial amounts of Federal funds. These locally created entities administer numerous programs funded by other Federal, State and private agencies/organizations most of which receive administrative funds for their operations. CAAs receive on an average of about 12 percent of their funding from CSBG. CSBG funds were never intended to be their sole source of support.

In addition, the Emergency Community Services Homeless Grant Program (EHP) funds may be used to support administrative expenses at the CAA level (but not at the State level) for homeless activities. Also, President Bush has requested full funding of $42 million for FY 1990 for the EHP program. Appropriations of $18.918 million were provided for FY 1989 for this program.

Question. How has the money under the Homeless Block Grant been used?

Answer. The Emergency Community Services Homeless Grant Program (EHP) is operated as a block grant, with funds allocated by formula to States, territories, and federally-recognized Indian tribes. Those grantees have reported to us that the funds are generally used to assist homeless families and individuals in the following ways:

- o emergency and transitional shelters/housing
- o food provided through pantries
- 0 medical and/or transportation services
- o case management
- o counselling on drug abuse, domestic violence and runaways
- o referral to other agencies, groups and/or services
- o clothing, blankets and emergency services
- o housing locator and placement assistance
- o education and employment training
- o employment placement assistance and hiring incentives to private sector organizations
- o outreach assessment and counselling
- o fund solicitation from companies and corporations
- o promotion of fund raising efforts to help build or buy buildings for conversion into shelters
- o day care

In addition, amendments to the Mckinney Act allow a State to spend up to 25% of its funds after October 1, 1988, to prevent homelessness under certain circumstances. Some States have advised us that they intend to use such funds for cash assistance payments to prevent eviction, foreclosure, or termination of utility services. Others may use the funds to hire counselors or provide other services to prevent homelessness.

Question. How many local agencies are receiving CSBG funding in FY 1989? How does this compare with 1982?

Answer. FSA does not fund CAAs directly and States are not required to report the number of sub-state grantees receiving CSBG funds; however, this information is available at the State level.

Question. What percentage of the United States' poverty population lives in localities served by Community Action Agencies?

Answer. FSA does not require states to report this information.

Question. Have States supplemented CSBG funds? If so, how many and how much? Is the support increasing? Do you have a State by State breakdown of this support?

Answer. Some States supplement CSBG funds; however, we do not require States to report this information. In FY 1989 the following States voluntarily indicated in their applications that they have appropriated funds to support CSBG activities.

Alabama--$90,000
Massachusetts--$250,000
Michigan--$2,900,000

Question. The CSBG Demonstration Partnership Program has been funded for three years. Have the programs been successful? Have they been able to raise the private match for poverty programs? Has the Department done any evaluation of the demonstrations supported by the program? If so, what were the results?

Answer. The first Demonstration Partnership Program projects were funded effective October 1, 1987. In FY 87 five projects were funded and twelve projects were funded in FY 88. (Grants are currently being processed for FY 89.) None of these grants have terminated; therefore we have no final data on these projects. However, we can offer these observations from our reviews of applications and information received in progress reports submitted by grantees: There does not appear to be a discernible pattern of private sector contributions in this program. The common contribution made by the private sector has probably been through the provision of employment and job training opportunities. Private foundation contributions are not generally part of the DPP projects although they do occur, e.g. the substantial participation of the Wilder Foundation in the project conducted by Ramsey Action Programs in St. Paul, Minnesota. Each project under the Demonstration Partnership Program contains a third-party evaluation component that is focused on determining the project's outputs, the value of the outputs, and possible improvements. This information, generated by the projects and the third-party evaluations, will be evaluated, processed, and disseminated for utilization to the State CSBG offices and community action agencies.

OFFICE OF HUMAN DEVELOPMENT SERVICES

STATEMENT OF ROBERT STOVENOUR, DIRECTOR, OFFICE OF MANAGEMENT SERVICES

ACCOMPANIED BY DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING REMARKS

Senator HARKIN. The subcommittee will resume its sitting.

The Office of Human Development Services manages programs for children, youth, and families, the elderly, persons with developmental disabilities, and native Americans. All these programs have a common goal, to help people maintain self-sufficiency, lead productive lives and overcome abuse, and the need for institutionalization.

While level funding is proposed for the majority of programs in this account, President Bush has proposed increases in some programs such as Head Start.

I have been and remain very concerned that the Federal role in providing support for these programs remains strong. On the other hand, I am very concerned over the growing administrative costs of foster care, and I want to discuss that with you two gentlemen this afternoon.

Before we begin this discussion on the administrative cost for foster care, I want to reiterate my strong support for the Federal role in protecting our children. I am concerned, however, especially in today's tight budget climate, when administrative costs have risen by 868 percent since 1981 and foster care maintenance costs have risen by only 52 percent during that same period of time.

PREPARED STATEMENT

So Mr. Stovenour, if you would please summarize your statement, and we will include your entire statement in the record.

Mr. STOVENOUR. Yes, sir; thank you very much. I have submitted the statement for the record. I would be pleased to answer questions.

[The statement follows:]

STATEMENT OF ROBERT STOVENOUR

I am here to talk about the Office of Human Development Services budget for Fiscal Year 1990.

First, I would like to discuss the priorities within the Office of Human Development Services which have been highlighted in President Bush's Budget: expanding Head Start, encouraging adoption, combatting homelessness and ending the scourge of drugs.

President Bush's Fiscal Year 1990 budget for Head Start provides the largest single-year increase in the program's 25 year history. President Bush has proposed to increase Head Start funding to $1,485,000,000, $250 million over the 1989 appropriation level. The additional funds would allow up to an additional 95,000 four year old children from low-income families to participate in Head Start's educational, medical, nutritional and social development programs.

President Bush's 1990 budget request supports adoption by promoting the adoption alternative and encouraging permanent adoptive placement of special needs children. In addition to restoring and doubling the tax deduction for adopting special needs children, President Bush proposes to fund the Adoption Assistance program at the full current services level of $125 million in 1990, 12% above the 1989 level. These funds will provide monthly payments to adoptive parents of 44,000 adopted children; reimbursements to adoptive parents who incur one-time costs in the process of adopting a special needs child; administrative support for special needs adoption programs; and training to staff in the field of special needs adoption. In addition, President Bush's 1990 budget provides $6 million for the Adoption Opportunities research and demonstration program which eliminates barriers to adoption.

For programs aimed at combatting homelessness and preventing drug abuse, President Bush provides $119 million, an increase of $43 million over the 1989 level for these programs.

- The 1990 request maintains the 1989 level of $27 million for the Runaway and Homeless Youth program, and two drug education and prevention programs authorized by the Anti-Drug Abuse Act of 1988: one aimed at runaway and homeless youth, $15 million; and the other serving children at-risk for involvement in youth gangs, $15 million.

- In addition, President Bush's budget seeks to fully fund in the Office of Human Development Services two McKinney Act programs for the homeless. Emergency Community Services for the Homeless funds are increased from $19 million in 1989 to $42 million in President Bush's 1990 budget request. This program provides emergency transitional services, such as food, shelter, medical care, children care, job training and counseling, to the homeless. President Bush also proposes to fund the shelter demonstration authorized by Section 903 of the Stewart B. McKinney Homeless Assistance Act of 1988. The Act authorizes one-time funding of $20 million, to remain available until expended. Funds would be granted to two or three States to build or rehabilitate apartment-style shelters.

The funding for other Human Development Services programs are contained in the residual freeze category, which includes numerous programs across the government. For all these programs, in aggregate, 1990 outlays would not exceed total outlays for such programs in 1989. This does not mean that each Federal program within this category must be frozen. The freeze is flexible in that it allows for negotiations between Congress and the Administration to determine appropriate funding priorities.

The Administration has identified two methods for achieving this aggregate outlay freeze -- 1) proceed with the consideration of Reagan Fiscal Year 1990 proposals, or 2) use the Fiscal Year 1989 outlays as the outlay level for Fiscal Year 1990.

The budget proposes to maintain 1989 funding levels for most Office of Human Development Services programs. Service levels will be maintained, and in some areas, increased, due to management and program operation efficiencies.

As 1990 budget negotiations between the Administration and the Congress move forward, to facilitate discussion we are treating the Reagan budget proposals as Bush Administration proposals. I would now like to outline for you some of the key features of those budget proposals.

- The full authorization level of $2.7 billion is requested for the Social Services Block Grant to continue support for a wide variety of social services in each State.

- The budget includes $277 million for programs designed to serve children and families at risk. These programs include Child Abuse State Grants, Family Violence Prevention Grants, Child Development Associate Scholarships, and Child Welfare Services.

- The budget includes $724 million for Administration on Aging programs providing nutrition and social services to approximately 9 million older Americans.

- The budget also provides $80 million for Developmental Disabilities programs to assist States ensure access to a wide range of services, including protection and advocacy,

for persons with developmental disabilities and their families.

- For 1990, $30 million is provided to promote the social and economic self-sufficiency of Native Americans.

- For Human Services Research, Training and Demonstration programs, $93 million is requested to support discretionary activities in the area of child abuse, child development, child welfare, aging and developmental disabilities. This request is a consolidation of many discretionary grant programs which are displayed together because of their similar purposes.

- A level of $69 million is requested for Program Direction to support 1,004 full-time equivalents.

For Foster Care, the current law estimate for 1990 is $1,161,000,000. Of this amount, $618 million would provide federal assistance for maintenance payments made on behalf of a monthly average of approximately 125,000 children. The remaining $543 million would provide for State and local administration of the program and training in the field of foster care.

In addition, a 1989 supplemental appropriation request of $423 million will be requested under the Foster Care program to meet eligible prior year claims.

Thank you, Mr. Chairman. My colleagues and I will be happy to answer any questions you and the Committee may have.

FOSTER CARE ADMINISTRATIVE COSTS

Senator HARKIN. I appreciate that. You are very kind.

Mr. Stovenour, as you can see from the charts my staff have prepared here, administrative costs for foster care have increased dramatically from $295 for a child in 1981 to $4,277 for a child in 1990. I guess that is projected right.

Mr. STOVENOUR. Yes, sir.

Senator HARKIN. You will also note from these charts that the number of children served has remained relatively stable. That is what I find intriguing. That is the second chart, the middle chart. The number of children served has increased by only about 8 percent since 1981.

How would we account for these increases? Do they reflect increases in services, protections, improvements in case management? What are they? Why is there an 868 percent increase?

Mr. STOVENOUR. It is, in fact, a very complex problem, one that we obviously are aware of, have been concerned about, and are doing something about.

If I could just for a moment discuss what is included in administrative costs, I think you will see that it is a term that may lead one to conclude that it is something which it is not.

Under the Foster Care Entitlement Program, the State agencies can charge a variety of costs to the program for which they can then submit bills to the Federal Government. The kinds of things that go into the administrative cost category include such things as referral to services, preparation and participation at judicial determinations, the placement of the child, development of the case plan, case management, supervision and reviews, recruitment and licensing of foster homes and institutions, payments for negative eligibility determinations, and payments of preplacement administrative costs for children who are later determined not to be IV-E eligible.

I think you are aware, Senator, that these costs are related to children who are eligible under AFD.; So there are a variety of costs that may be legitimately claimed.

Since the beginning of the program the States have begun to shift some costs that in some cases probably had been paid for either from State resources or from other Federal resources such as the social services block grant program. States have more recently been allocating those costs associated with the foster care program to this program, and, as a result of these shifts, the legitimate claims have risen substantially.

Senator HARKIN. Now wait a minute. I do not know that I understood that last thing you just said now. The number of children served has gone up only 8 percent. Now these administrative costs, you said there were a variety of costs, and you just listed a whole bunch of them in there that go into it.

Were those costs not present 8 years ago?

Mr. STOVENOUR. In many cases they were; however, there are several things that must be considered. The foster care program was designed to achieve specific goals to help improve the foster care programs in the States. Many improvements in the program are related to the kinds of things that I have listed for the protec-

tion and well-being of the children. Associated costs may have been part of the States' programs or may have been charged to other State or Federal programs.

States have been shifting costs previously supported by other sources of funding to the foster care program. In many cases, the kinds of things that are provided under the foster care administrative cost category are required by the foster care legislation to ensure the protection and well being of the child.

FOSTER CARE AUDIT

Senator HARKIN. Have you done an audit to determine if there has been a shift in cost to the foster care program?

Mr. STOVENOUR. We have done several administrative cost reviews of the States. The inspector general has also done a review of administrative costs and generally found that the costs as I have indicated here were allowable under the very broad definition provided in law. They did find considerable shifting.

QUALITY OF FOSTER CARE

Senator HARKIN. Again, I am a big supporter of the foster care program. It is a great program. When you look at the other chart over there for administrative costs with the lines across, it looks like the maintenance payments and administrative costs are going to cross here in about another year or so.

I guess what you are trying to tell me is that perhaps the qualitative aspects of the foster care program are a lot better today than they were 3 years ago. It has doubled almost in 3 years. In 4 years it has definitely doubled. You are telling me that these costs have gone up. I thought I heard you say something about increased care and that kind of stuff, and I am asking, have the qualitative aspects of the program increased that much?

Mr. STOVENOUR. We cannot correlate the increased cost with any clear indications of the quality of the programs in the States.

Senator HARKIN. You cannot?

Mr. STOVENOUR. We cannot.

ADMINISTRATIVE COSTS—SOURCES OF SUPPORT

Senator HARKIN. So that raises a suspicion in my mind that what we are seeing here is more of a shift than anything else from what States traditionally spend. Now they are just shifting it onto this to make the Federal Government pick it up.

Mr. STOVENOUR. The findings we have do indicate that that is the case in many instances. That is not to say that what the States are doing is in any sense illegal. That is not the point I am trying to make.

The point is that they are shifting these costs. In many cases costs of services have gone up. There is probably no question about that. You can see the clear indication here that the foster care program is assuming larger proportions of these costs.

RATIONALE FOR ENTITLEMENT NATURE OF ADMINISTRATIVE COSTS

Senator HARKIN. You operate a number of programs that are of critical importance to children and youth; for example, child abuse State grants, assistance for runaway youth and homeless, family violence protection, child abuse, challenge grants, adoption opportunities, independent living, et cetera.

None of these programs has uncapped an open-ended administrative cost as does the foster care program; is that correct?

Mr. STOVENOUR. That is correct, yes.

Senator HARKIN. What rationale is there for the foster care administrative costs to be open-ended when this does not apply to any of the other children's programs?

Mr. STOVENOUR. I think part of that goes back to the history of the program when it was initially created. It has always been an entitlement program, and I think its relationship to the AFDC Program probably accounts for some of the philosophy for maintaining it as an entitlement program.

LEGISLATIVE PROPOSAL

Senator HARKIN. President Reagan proposed to cap the administrative costs, but President Bush has proposed to leave it open-ended; is that correct?

Mr. STOVENOUR. Yes, sir; there was a proposal associated with the Reagan budget that assumed a legislative change which would combine these administrative costs, training costs, and independent living activities with the Child Welfare Services Formula Grant Program. That is a much broader authority that the States have for providing a broad variety of services for children. Under that proposal costs would have been capped.

The Bush adminstration would, I believe, prefer to look at this program as it relates to other initiatives of the new administration and see if there are any other things that ought to be included in a legislative proposal. It is still under active consideration.

That would mean that the maintenance payments for the provision of foster care, the payment for the children in homes, would remain an entitlement program. The other activities would be part of a capped formula grant program.

OTHER HDS CHILDREN'S PROGRAMS

Senator HARKIN. Now all of these other child programs I talked to you about are not tied to AFDC, but they are entitlement programs?

Mr. STOVENOUR. The other programs are not entitlement programs.

Senator HARKIN. They are mandatory programs?

Mr. STOVENOUR. Most are formula grant programs, yes.

CONTROLLING ADMINISTRATIVE COSTS

Senator HARKIN. Are these administrative costs something we ought to be concerned about?

Mr. STOVENOUR. I believe we should.

Senator HARKIN. Are you making any recommendations on how to keep them under control?

Mr. STOVENOUR. As I mentioned, we are looking at some legislative proposals related to shifting the financing mechanism for the administrative costs of the program.

In addition, we continue to review these costs through our central and regional office staffs. We continue to review the eligibility of the children and the costs associated with the program. That is an ongoing effort that we will continue.

Mr. WILLIAMS. Senator, if I might amplify this a little bit on the point that Mr. Stovenour made. The current foster care program originated in 1980. Previously, foster care had been a part of the AFDC Program, so that both the maintenance payments and the administrative costs were part of an entitlement program. They were both matched by Federal dollars. They were both open-ended.

In 1980 when that program was separated from AFDC, the foster care parts of the program, the maintenance payments, and the administrative costs retained their entitlement nature. That is different than almost any other social service program that we administer.

The proposal that the Reagan administration had sent forward and which the Bush administration is still considering—and I say considering in a positive sense, not in any negative sense—was to take these administrative costs and try to treat them as we treat many other administrative costs; namely, as a discretionary part of the program rather than as an entitlement to the States.

The proposal is to take those administrative costs and combine them with another program which funds essentially the same sort of activities, the child welfare services program, where the same sort of social service and administrative components exist for a broad array of children and not just the AFDC children.

The idea was to make those resources available so that the dollars would be available to provide the social services that were needed, and also provide a context where there would be some discipline in how those resources would be used. Costs would not be totally open-ended.

CLAIM PERIOD

Mr. STOVENOUR. Just one other point, Mr. Chairman. The States have 2 years in which to submit claims under the entitlement program. That has provided some difficulties in the past.

Senator HARKIN. Now does that have to be changed legislatively, or can you change that administratively?

Mr. STOVENOUR. The 2-year claim period would have to be changed legislatively.

Senator HARKIN. So that is a requirement in law?

Mr. STOVENOUR. Yes, sir.

Senator HARKIN. How long has that been in law, do you know?

Mr. STOVENOUR. It was part of Public Law 96–272, which was enacted in 1980.

Senator HARKIN. Would it work if we just had a 1 year?

Mr. STOVENOUR. I am sorry, sir?

Senator HARKIN. Could you work it administratively if you just had a 1 year?

Mr. STOVENOUR. I think that would improve the situation if it were a 1 year.

Mr. WILLIAMS. We have other programs where the States have 2 years to claim reimbursement.

Senator HARKIN. I am sorry. What was that?

Mr. WILLIAMS. States have 2 years to claim reimbursement for service in other Social Security Act programs administered by the Department.

FOSTER CARE AUDITS AND REVIEWS

Senator HARKIN. How many reviews, audits, and site visits do you have budgeted for next year?

Mr. STOVENOUR. For 1990?

Senator HARKIN. Yes.

Mr. STOVENOUR. I do not have that figure. I know for this year we had planned to do 34 section 427 reviews.

Senator HARKIN. How many of those 34 are you actually doing?

Mr. STOVENOUR. We plan to complete 34 section 427 reviews. However, of the planned 32 IV-E reviews, we will complete 19 because of a shortage of salaries and expenses resources.

Senator HARKIN. Because of what?

Mr. STOVENOUR. Because of an increase in a number of uncontrollable costs, we have had to reduce support in areas we can control, such as travel.

Senator HARKIN. Would an increase in audits and reviews save us any money?

Mr. STOVENOUR. There is no question that some savings would occur.

A large part of the foster care population is in 10 or 11 of the largest States, and we do tend to concentrate on those States. The States that we review are the States where costs, particularly administrative costs, have increased dramatically. When the claims are submitted, if we have questions about claim eligibility we will defer payment on portions of their estimated costs.

WHAT IS INCLUDED UNDER ADMINISTRATIVE COSTS

Senator HARKIN. Now let me ask you this. If you look back at the history going back to 1981 or 1982 and you look at the list of the items that were included under the title of administrative costs, if you list all the things that the States put in for administrative costs for foster care and then you compare it to the list you have now, the list now would be substantially longer than what the list was in 1981; is that right?

Mr. STOVENOUR. I do not believe we have any information that would substantiate that. I would assume that would be the case.

Senator HARKIN. That would have to be the case.

Mr. STOVENOUR. I would assume that to be the case, yes.

Senator HARKIN. If it were not the case, if you had the same list of items, then we would really seriously have to look at how each one of those incrementally went up 800 plus percent.

You see, I gathered from what you said to me initially was that what States are doing is that they are putting more and more of what they had originally done under the purview of administrative cost, you see, and that way getting the Federal Government to pick up the tab. As long as they know it is an open-ended entitlement, why, just throw in the kitchen sink, throw in everything.

What I would like to know is could you provide for me a list of what were administrative costs, let us say, in 1981 that would have been approved and what administrative costs you are approving today.

Now, you do not approve every administrative cost?

Mr. STOVENOUR. No, sir; as I mentioned to you, there are reviews that do go on. As we review and identify costs which are inappropriate or not eligible under this program disallowances are made.

NATIONAL REVIEW OF FOSTER CARE

Senator HARKIN. Have you done a national program review or audit of this whole program?

Mr. STOVENOUR. No, sir.

Senator HARKIN. Why not?

Mr. STOVENOUR. I think we have concentrated on looking at the way in which the States themselves have administered and managed the program. We have not done a national review.

Senator HARKIN. It would seem to me a national review of this program, an audit of this program, would show us some places where we could tighten down on the program.

I guess what I am really concerned about is you have the same number of kids, there is no indication that the qualitative care is any better today in foster homes than it was 6, 7, 8 years ago. Yet, these administrative costs have just skyrocketed. I mean, I am suspicious that States, knowing this is now an open-ended entitlement, are throwing anything that can even be remotely linked to this.

Mr. STOVENOUR. Well, in some cases that may be true. I think there is also a definitional problem in the legislation which is very broad as far as what is allowable here. We have not had a lot of success in trying to limit the broad definitions more than what are specified in the law.

ADMINISTRATIVE COSTS BEING INCURRED

Senator HARKIN. Would you support a national audit to find out just what the States are charging us for on these administrative costs? Then you could have a handle on which way to go.

Mr. STOVENOUR. For the most part, from what we have learned through our reviews, we can determine where the problems are and what kinds of costs are being incurred.

Senator HARKIN. Could you furnish that for us?

Mr. STOVENOUR. We can give you the findings we have come up with from our cost reviews.

Senator HARKIN. I would like to know that. I would like for you to spell out for us what are all these administrative costs, and I would like to know how they vary from State to State.

[The information follows:]

There are a few different ways at looking at these costs. First, for the several States for which we have detailed information, the costs are divided between local agency activities, where the direct services are provided, and the central office of the State agency by percentages that vary from 52 to 86 percent. Most of these States are over 80 percent local costs. Second, for the smaller group of States where we have more detailed information, case management activities make up from 70 to 74 percent of all the activities conducted. These are the services aimed directly at helping the children and their families.

COMPARISON AMONG STATES

Senator HARKIN. Another thing I would like to do is start comparing some States and see what it looks like in those States. Are some States going up more rapidly than others?

Mr. STOVENOUR. Yes, sir; some are going up more rapidly than others.

Senator HARKIN. I would like to look at what their administrative costs are compared to other States. That is why you need this national audit, this national review.

Please supply those to us because I would like to find out and get a handle on this. That has got to be very disturbing. If you look at the number of children served and you follow that line and look over there at the maintenance payments, they follow about the same line. If you look at the administrative costs, they just skyrocket.

[The information follows:]

FOSTER CARE
Administration

Name of State	FY 1985	FY 1986	Increase Greater Than 10%
Alabama	265,483	270,393	
Alaska	0	0	0
Arizona	1,304,637	1,567,210	20.13%
Arkansas	89,411	214,086	139.44%
California	50,476,603	52,614,451	
Colorado	5,854	28,426	385.58%
Connecticut	859,227	1,227,348	42.84%
Delaware	79,172	1,815	
Dist of Col	2,766,581	2,550,216	
Florida	617,305	1,022,382	65.62%
Georgia	3,606,019	4,323,994	19.91%
Hawaii	13,552	22,851	68.62%
Idaho	27,968	21,171	
Illinois	3,920,237	4,468,456	13.98%
Indiana	264,756	236,934	
Iowa	705,667	1,053,947	49.35%
Kansas	731,426	803,157	
Kentucky	20,989	916,832	4,268.15%
Louisiana	5,057,858	5,211,218	
Maine	911,938	1,153,580	26.50%
Maryland	3,897,566	7,701,641	97.60%
Massachusetts	2,126,993	2,446,748	15.03%
Michigan	11,189,136	21,320,681	90.55%
Minnesota	4,628,374	4,845,794	
Mississippi	80,156	70,699	
Missouri	7,537,323	7,619,488	
Montana	353,596	427,265	20.83%
Nebraska	1,178,704	1,120,016	
Nevada	25,732	26,384	
New Hampshire	475,452	458,355	
New Jersey	2,504,411	8,135,057	224.83%
New Mexico	1,215,400	1,227,026	
New York	36,447,061	54,726,340	50.15%
North Carolina	157,029	166,937	
North Dakota	87,510	206,306	135.75%
Ohio	7,545,906	11,823,707	56.69%
Oklahoma	1,254,936	1,541,676	22.85%
Oregon	2,302,526	2,913,103	26.52%
Pennsylvania	10,708,845	6,596,378	
Rhode Island	171,520	821,677	379.06%
South Carolina	665,288	724,267	

South Dakota	13,499	20,096	48.87%
Tennessee	30,077	39,974	32.91%
Texas	2,503,397	4,331,433	73.02%
Utah	419,484	522,519	24.56%
Vermont	1,088,532	1,090,523	
Virginia	448,226	455,746	
Washington	1,870,781	2,398,673	28.22%
West Virginia	2,880,234	3,443,028	19.54%
Wisconsin	6,874,079	7,398,721	
Wyoming			
TOTALS	182,406,456	232,328,725	

Name of State	FY 1987	Increase Greater Than 10%
Alabama	173,656	
Alaska	0	
Arizona	1,769,385	12.90%
Arkansas	481,136	124.74%
California	65,748,800	24.96%
Colorado	946,191	3228.61%
Connecticut	1,418,037	15.54%
Delaware	0	
Dist of Col	2,405,616	
Florida	1,278,686	25.07%
Georgia	4,620,981	
Hawaii	13,731	
Idaho	35,777	68.99%
Illinois	11,384,484	154.77%
Indiana	278,814	17.68%
Iowa	1,619,096	53.62%
Kansas	871,303	
Kentucky	1,137,167	24.03%
Louisiana	5,873,380	12.71%
Maine	1,637,684	41.97%
Maryland	9,568,982	24.25%
Massachusetts	1,689,304	
Michigan	18,497,743	
Minnesota	5,190,218	
Mississippi	41,411	
Missouri	7,945,445	
Montana	304,167	
Nebraska	986,533	
Nevada	30,638	16.12%
New Hampshire	663,595	44.78%

New Jersey	7,391,548	
New Mexico	1,440,948	17.43%
New York	71,741,093	31.09%
North Carolina	196,693	17.82%
North Dakota	268,340	30.07%
Ohio	9,225,344	
Oklahoma	1,729,165	12.16%
Oregon	3,610,559	23.94%
Pennsylvania	7,058,711	
Rhode Island	1,214,128	47.76%
South Carolina	1,439,792	98.79%
South Dakota	33,653	67.46%
Tennessee	49,934	24.92%
Texas	8,984,028	107.41%
Utah	539,718	
Vermont	1,735,197	59.12%
Virginia	498,888	
Washington	2,664,826	11.10%
West Virginia	2,821,740	
Wisconsin	7,581,427	
Wyoming		
TOTALS	276,837,692	

RUNAWAY AND HOMELESS YOUTH PROGRAM

Senator HARKIN. Let me just ask a couple of questions about the runaway and homeless youth program. It is designed to address crisis needs of youth, funding 333 temporary shelters with $26.9 million. There are an estimated 1 million youth who run away or are pushed out of their homes each year.

I have heard from my State of Iowa and I am told that they are turning away young people who come to the shelters simply because they do not have room.

Have you done an assessment to determine the unmet needs for runaway youth services?

RUNAWAY AND HOMELESS UNMET NEEDS

Mr. STOVENOUR. Senator, I am not aware that there has been an assessment of unmet needs. I think there is an ongoing understanding of the problem for these children, but I do not know that there has been an assessment.

I will try to supply that for the record.

Senator HARKIN. Please find out for me.

[The information follows:]

An assessment to determine the unmet needs for runaway youth services has not been undertaken. However, the General Accounting Office has been conducting several studies over the past year to determine the number of homeless in America, including a specific estimate of the number of runaway and homeless youth in America. The results of these studies are not yet available. We have been told to expect them sometime this summer.

DEPENDENT CARE PROGRAM

Senator HARKIN. You are proposing to eliminate funding for the Dependent Care Planning and Development Program which last year provided $11.8 million in seed money to establish child care information and referral centers as well as services for latchkey children. Your budget justification says the program has been successful but is no longer needed.

Are you implying that the Nation's child care problems have been solved or that the States just do not need this money? What do you mean when you say it is no longer needed?

Mr. STOVENOUR. I believe the program was conceived and put into place as a planning and development program, the focus of which is increasing public awareness and assisting States in coming up with innovative approaches to problems of latchkey children.

We believe that the child welfare services program and the social services block grant program can provide resources to meet those needs.

FRAIL ELDERLY

Senator HARKIN. Let me talk a little bit about the frail elderly. The fastest growing segment of our population are people over age 85. I might just add that Iowa has the highest percentage of any State population of people over 85 as compared to the entire population.

In view of the growing number of the oldest members of the population who are in greatest need of home and community-based long-term care services, what is your rationale for requesting level funding of only $4.8 million for in-home services for the frail elderly?

Mr. STOVENOUR. This is a new program. There are resources available from formula grant programs in the Administration on Aging and the social services block grant to support the services to those most in need.

DEVELOPMENTAL DISABILITIES

Senator HARKIN. Let me ask a couple of questions about developmental disabilities. How have the States responded to the 1987 mandate that developmental disability funds be used for capacity building rather than provision of services?

Mr. STOVENOUR. I think the response has been very good. As you know, a report is required to be sent to the Congress by 1990 which requires an assessment of the total system to provide services to severely disabled people.

We have been working with them through the developmental——

Senator HARKIN. We cannot hear you.

Mr. STOVENOUR. We have been working with the State developmental disability councils through the Administration on Developmental Disabilities to develop that report. I think the State councils themselves have responded positively to this idea of seeing

themselves in a role as a catalyst, as a planner, as an advocate for the severely disabled.

I think that they have responded quite well.

Senator HARKIN. I am sorry?

Mr. STOVENOUR. The States have responded quite well to that mandate.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Mr. Stovenour and Mr. Williams, thank you very much. Those are all the questions I have that I wanted to cover with you today. I have some more to submit to you in writing.

I look forward to your sending us the information we asked for on the foster care program, and I would like to have that list of administrative costs and any data you have on the States and comparison of the States and how those costs have increased.

Mr. STOVENOUR. Yes, sir.

Senator HARKIN. We will take a look at that and see if we need to get some more data.

Thank you very much.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

FOSTER CARE ADMINISTRATIVE COSTS

Question. As you can see from the charts, administrative costs for foster care have increased dramatically, from $295 per child in 1981 to $4,277 per child in 1990. You will also note from these charts that the number of children served has remained relatively stable--the number of children served has only increased by about 8 percent or 23,000 to 25,000 since 1981. Do these increases in costs reflect increases in services, protections, or improvements in case management?

Answer. In the early years of this program, we believe that the States made substantial improvements in protections and case management with funding increases. In later years, however, our best information indicates that States have been "Federalizing" their foster care; that is, they have shifted the costs of providing services for their foster children from the State to the Federal Government. Many of these costs have been shifted in a legitimate way, within the law and regulations.

Question. We must do everything we possibly can to protect our children. I am not talking about cutting programs that protect our children from horrendous situations in the home; however, I am concerned over the rising costs of administrative services. With limited federal dollars, we must ensure that every dollar we spend does provide protection for our children, and is not just frittered away. Has the Department done a national audit or program review to determine whether these costs are related to direct services to children or to determine if these increases are related to a shift in the costs to the foster care program that have traditionally been borne by the states or other federal programs?

Answer. The Office of the Inspector General (OIG) conducted such a review. They found that there was little measurable information available. However, the best information OIG Staff was able to obtain and the information we have received through other avenues indicate that cost shifting is the major use of the funds. At the same time, we have learned that the amount of services delivered has also increased.

Question. You operate a number of programs that are of critical importance to children and youth. For example:

child abuse state grants ($11.6 Million in 1989) assistance for runaway and homeless youth ($26.9 million in 1989) child welfare assistance ($246.7 million in 1989) family violence prevention ($8.2 million in 1989) child abuse challenge grants ($4.8 million in 1989) dependent care planning and development (also known as the latchkey program ($11.8 million in 1989) adoption opportunities ($5.0 million in 1989) independent living ($45.0 million in 1989)

None of these programs has uncapped and open ended administrative costs as does the Foster Care program. Is that correct?

Answer. Yes, that is correct.

Question. What rationale is there for Foster Care administrative costs to be open ended when this does not apply to any of the other children's programs?

Answer. The Foster Care program is an open-ended entitlement program, like the AFDC entitlement program, based on the fact that only children categorically eligible for AFDC are eligible for Title IV-E foster care. Historically, the AFDC-Foster Care program was enacted in the 1950's and was the predecessor program to the existing Title IV-E program.

Question. This seems of particular concern since administrative costs have increased 868 percent since 1981 while maintenance costs paid to support children in foster care settings have increased only 52 percent since 1981. President Reagan proposed to cap administrative costs but President Bush has proposed to leave it open ended. Is that correct?

Answer. The legislation was proposed in the Reagan budget. It is under review by the Bush Administration.

AUDIT ACTIVITY OF FOSTER CARE ADMINISTRATIVE COSTS

Question. The March 25, 1989 edition of The Washington Post carried a story about the Department trying to recover about $7.8 Million in Foster Care administrative cost reimbursements which the District of Columbia was not entitled to. How often does the Department conduct a review or audit of claims submitted by the states for foster care maintenance and administrative costs?

Answer. Our planned schedule is to conduct a review of the Title IV-E-Foster Care claims of the four largest States annually and of the other States every three years. The Office of the Inspector General/Audit Agency (AA), which conducted the review you referred to, conducts reviews from time to time, based on matters of concern to them and us. Also, when there are special sets of claims that raise special problems, our regional staff conducts reviews.

FOSTER CARE

Question. How many reviews, audits and site visits do you have budgeted for fiscal year 1990?

Answer. We have not budgeted for reviews for fiscal 1990 since we do not know what funds will be available.

We would like to do 17 Section 427 reviews.

Depending on funds availability, we will do 15-20 Foster Care reviews and 5-10 Adoption reviews.

Question. Do you feel that an increase in audits and reviews would save money?

Answer. Yes, it probably would. But our real objective is to assure that Federal funds are spent for the purposes intended in the law.

Question. In view of the fact that these costs continue to rise, why aren't you conducting more reviews of the claims submitted by States?

Answer. We have not been able to conduct more reviews because of the lack of funds in the salaries and expenses account.

FOSTER CARE SUPPLEMENTAL

Question. A March 28,1989, article in The New York Times stated that the State of New York has filed suit to recover $156 million in child welfare payments that have been withheld by the Department. The Department has submitted a fiscal year 1989 supplemental request for administrative costs of $423,345,000 to cover amounts owed States for fiscal years 1987 and 1988. Is your fiscal 1990 budget request sufficient to cover remaining prior year claims to the states, or are we going to be revisiting this again in another supplemental?

Answer. We believe that the supplemental appropriation request would enable us to reimburse the States for FY 1987 and FY 1988 allowable claims as we currently estimate them. However, under the law States have two years in which to submit revised claims after each fiscal year ends.

RUNAWAY YOUTH SERVICE

Question. The Runaway and Homeless Youth Program is designed to address crisis needs of youth, funding 333 temporary shelters with $26,923,000. There are an estimated one million youth who run away or are pushed out of their homes each year. I have heard from my State of Iowa, and I am told that they are turning away young people who come to the shelters, simply because they do not have the room. Have you done an assessment to determine the unmet need for runaway youth services.

Answer. No. However, the General Accounting Office has been conducting several studies over the past year to determine the number of homeless in America, including a specific estimate of the number of runaway and homeless youth in America. The results of these studies are not yet available to us, though we have been told to expect them sometime this summer.

Question. Do you have national data on how many youth must be turned away from fully occupied shelters?

Answer. No, we do not have this information available.

FAMILY REUNIFICATION

Question. What efforts are underway geared to prevention, and family reunification?

Answer. In our runaway and homeless youth centers, reunification of the young client with his family is a primary objective. More than one half of the youth served are reunited with their families. The follow-up counseling and other support

services offered to the clients and their families focuses on identifying and addressing family problems before they reach crisis proportions.

CHILD CARE PROBLEMS - DEPENDENT CARE

Question. You are proposing to eliminate funding for the Dependent Care Planning and Development program, which last year provided $11,856,000 in seed money for localities to establish child care information and referral centers, as well as services for "latchkey" children. Your budget justification says that the program has been successful, but is no longer needed (page 7). Are you implying our nation's child care problems have been solved, or that the States don't need this money?

Answer. The President's FY 1990 request for Dependent Care Planning and Development Grants does not imply that the nation's child care problems have been solved or that states have no need for child care funds. Rather it indicates that these grants, which have been available since FY 1987 as seed money "to assist states in the planning, development, establishment, expansion and improvement of services," have been successful in helping to establish dependent care programs. States can continue to operate these programs with Federal assistance with funds provided through either the Social Services Block Grant or the Child Welfare Services program. However, given the situation with the Federal Budget, we believe that the nation's child care problem could be addressed in a more effective and efficient manner through the use of expanded state resources.

Question. What evidence do you have that States could provide such funds through their social services block grant or child welfare services programs, as you have proposed, without reducing other services?

Answer. While we do not have hard evidence that States could provide such funds through their social service programs, we believe the assumption is valid.

Question. How will this be accomplished?

Answer. Because of serious budget constraints at the Federal level, States will be faced with a number of tough choices, but nevertheless will have the ability to make the tough decisions and continue services under this program.

COMPREHENSIVE CHILD DEVELOPMENT PROGRAM

Question. Last year, Congress provided $19,760,000 for first-year costs of the recently authorized comprehensive child development program. What is the status of implementing this program?

Answer. The announcement soliciting applications for both planning and operating grants under the Comprehensive Child Development Program (CCDP) was published in the Federal Register December 29, 1988. The closing date for planning grants under

this announcement was February 15, 1989. The 291 applications which were received were reviewed by panels of individuals knowledgeable about child development. Thirty of the highest ranking applications have been funded with a project start date of April 15, 1989. These 30 grants total approximately $840,000 and will last three months.

July 14, 1989 is the due date for operating grant applications under this program. We are currently preparing for the receipt and paneling of these applications.

Question. How many grant applications do you expect to receive, and how many will you fund?

Answer. Our prediction is that we will receive between 400 and 500 operating grant applications. In accordance with the Act we will fund no fewer than 10 and no more than 25. They will be funded before the end of fiscal year 1989.

Question. Why isn't there any money in your fiscal 1990 budget for a second round of new grants?

Answer. Part E of Public Law 100-297 authorized appropriations at $25,000,000 for each of fiscal years 1989 through 1993; $19,760,000 was appropriated for fiscal year 1989. We believe that it is the intent of the legislation to fund the same operating grantees selected for funding in fiscal year 1989 in each succeeding year of the five year program.

DEVELOPMENTAL DISABILITIES CAPACITY - BUILDING

Question. How have States responded to the 1987 mandate that developmental disabilities funds are to be used for capacity-building activities rather than for provision of services?

Answer. As a result of the changes required by P.L. 100-146, State Developmental Disabilities (DD) Planning Councils revised their three year State Plan goals and objectives. Annual Program Performance Reports submitted for fiscal years 1987 and 1988 describe activities and accomplishments which demonstrate that funds are being directed to systems change rather than direct services to persons with developmental disabilities.

Activities such as stimulating interprogram coordination and funding, analyzing Federal and State legislation affecting people who have developmental disabilities, and initiating collaborative statewide employment efforts, public awareness campaigns, policy analysis, consumer surveys or training initiatives are examples of State involvement in capacity building on behalf of persons with developmental disabilities. Prior to implementation of the 1987 Act amendments, States reported the number of clients served under each Federally-mandated priority area. States are now reporting on Part B funds expended on employment, child development, case management and community living priority area activities and, where appropriate, on activities which address a State-specific priority area.

Question. Has this legislative mandate resulted in States getting greater value from their basic State grant funding?

Answer. The value States are receiving from their basic State grant funding can be measured by State efforts to focus on systemic change, the results of which are designed to impact on the larger service delivery system and developmental disabilities community. State activities are focused on improving and increasing the services available to a greater number of persons with developmental disabilities. Where previously DD funds have been used to provide direct services and to fill gaps, States are now targeting their resources on policy analysis, legislative and regulatory change, coordination activities and client empowerment.

State DD Planning Councils are supporting demonstration projects which assess needs, evaluate the quality and effectiveness of services, demonstrate model programs for providing services in the community, educate the public, develop systems for specialized services, and assist in adapting generic services on behalf of people with developmental disabilities. Developmental Disabilities Planning Councils are challenging systems to address complex issues in such areas as education, employment, housing, transportation, and the needs of aging persons with developmental disabilities, and this expanded use of program funds has enabled States to build capacities in individuals, families and in communities.

DEVELOPMENTAL DISABILITIES PRIORITY AREAS

Question. In addition to the four specified Federal priority areas, the 1987 amendments authorized a State priority area considered essential by the State Planning Council. To what extent has basic State grant funding been used on State priority areas, and what types of State priorities have been selected?

Answer. Seven State DD Planning Councils have identified State priority areas. Those States are: Arizona, Georgia, Kentucky, North Carolina, Oklahoma, Oregon and Wisconsin. In FY 1988, basic State grant expenditures on State priority areas totaled $437,729.

The priorities selected were independent living, family support, advocacy and training, public awareness, health, consumer self-advocacy and basic rights legislation.

State	State Priority Areas	FY 1988 Expenditures
AZ	Bridge to Independent Living	$ 80,574
GA	Family Support	69,392
KY	Advocacy and Training	160,722
NC	Public Awareness	31,533
OK	Health	61,508
OR	Consumer Self-Advocacy	9,000
WI	Basic Rights Legislation	25,000
	Total	$437,729

DEVELOPMENTAL DISABILITIES PROTECTION AND ADVOCACY

Question. The 1987 amendments authorized the Protection and Advocacy systems to investigate incidents of alleged abuse and neglect. Has this authority been used to intervene in the service delivery system?

Answer. In their FY 1988 Program Performance Reports for the first year since the enactment of the 1987 amendments, most States reported some activity in cases involving suspected or alleged instances of abuse and neglect.

In 52 States and other jurisdictions reporting, a total of 3285 cases involving suspected or alleged instances of abuse and neglect were reported. This is a small increase from FY 1987. The number of States reporting no cases involving abuse and neglect fell from 7 in FY 1987 to 2 in FY 1988.

Question. To what extent has this authorization increased the effectiveness of the protection and advocacy systems?

Answer. We believe the increase in the number of reported cases and the subsequent investigations have resulted in improved outcomes and circumstances for the individuals concerned.

Question. Have State Protection and Advocacy systems implemented the grievance procedures mandated in the 1987 amendments, and have these grievance procedures helped obtain access to appropriate services?

Answer. All Protection and Advocacy systems submitted assurances during FY 1988 that they were in compliance with the requirements for a grievance system. Some of the Program Performance Reports submitted by the Protection and Advocacy systems for FY 1988 (the first since the enactment of the 1987 amendments) mention that clients and would-be clients have been helped in obtaining appropriate services by this grievance procedure. The consumer survey contained in the report required for submission by each State by January 1,1990, should provide more detailed information on how effectively these procedures are working.

IN-HOME SERVICES TO FRAIL OLDER PERSONS

Question. We are experiencing a rapid growth in this country in the number of frail elderly persons who need special assistance to avoid institutionalization. I am particularly sensitive to this problem, since my home State of Iowa has the highest percentage of population over age 85 in the nation.

In view of the growing number of the oldest members of the population who are in greatest need of home and community-based long-term care services, what is your rationale for requesting level funding of only $4,834,000 for in-home services for the frail elderly?

Answer: Additional funds for this activity were not requested because there are other sources of funds available, including the Social Services Block Grant and Title III B of the Older Americans Act.

Question. If we appropriated the authorized level of $27,563,000 in fiscal 1990, is there any doubt the funds could be effectively used?

Answer. Additional funds could be effectively used if appropriated in Fiscal Year 1990. However, we are encouraging States and Area Agencies to increase service levels by effectively utilizing resources from the private and voluntary sectors, as well as the public sector. Federal resources will never be able to meet the entire need for services.

NUTRITION SERVICES

Question. Your budget proposes the same amount of funding for Older Americans Act supportive services and nutrition programs as they received in fiscal 1989, yet you indicate that the level of services will increase in fiscal 1990. How realistic is it to expect increased efficiencies and voluntary contributions to more than offset the impact of inflation?

Answer. Over the past several years, improved efficiency in program operations, leading to enhanced productivity, and increased voluntary contributions have proved very successful in offsetting inflation. We have no reason to believe that we will be any less successful in Fiscal Year 1990 in being able to offset inflation through increased program efficiencies and increases in the rate of voluntary contributions.

PROGRAM EFFICIENCIES

Question. Specifically, what efficiencies will be accomplished by the State and area agencies on aging?

Answer. Over the past several years the Administration on Aging (AoA)and the State and area agencies on Aging have undertaken a series of initiatives designed to increase the number of service units and meals provided to older persons. These initiatives include: increasing voluntary contributions and improving the accountability for these funds; implementing performance-based contracts (payment only for units of service which are actually delivered); and improving program and financial management. The Administration on Aging continues to work with State and area agencies to identify additional opportunities for improving existing service systems and making such systems more efficient.

OLDER AMERICANS ACT OUTREACH PROGRAMS

Question. The Older Americans Act authorizes $10 million to fund outreach efforts by State and Area Agencies on Aging, to inform elderly poor persons about their possible eligibility for Supplemental Security Income (SSI), Medicaid and food stamps.

Only half of all elderly poor persons who are eligible for these programs actually participate in them.

What is your rationale for not requesting an appropriation to implement this Older Americans Act outreach program?

Answer. Total appropriations ceilings would not permit the request of new funds for this activity in line with the control of overall expenditure levels and the promotion of a stable economy through deficit reduction. Nevertheless, the Administration on Aging has taken a number of positive steps to provide information for outreach efforts, as indicated below:

- During October 1988, Regional Program Directors on Aging were issued an AoA Directive (OSTP 89-01), transmitting copies of materials for use by the State Agencies on Aging in conducting outreach activities to older individuals. The Regional Program Directors were asked to contact the State Agencies and offer assistance in planning and organizing Statewide outreach campaigns.

- An Information Memorandum (IM-89-01) was issued to State Agencies during October 1988 informing them about outreach materials and the availability of these materials either from the AoA Regional Offices, American Association of Retired Persons (AARP) or the Villers Foundation.

- Arrangements were made for AARP and the Villers Foundation to respond directly to requests from State Agencies for SSI outreach materials. The State Agencies were provided with the names of contact persons at those organizations.

- Arrangements were made for the Social Security Administration (SSA) to send SSI outreach materials directly to the State Agencies. During the first quarter, SSA shipped approximately 25,000 copies of three separate items (two Fact Sheets and a Poster) to the State Agencies.

- In response to a request from SSA for assistance in disseminating information about SSI changes, on April 7, 1989, AoA issued an Information Memorandum (IM-89-08) to the State Agencies transmitting an SSA Fact Sheet describing two provisions of the SSI Program that were effective on July 1, 1988.

- AoA obtained 25,000 copies of the brochure, "Facts About The Food Stamp Program," from the Department of Agriculture's Food and Nutrition Service. These brochures were disseminated to the AoA Regional Offices for dissemination during January, 1989.

- AoA Regional Offices have provided outreach materials to the State Agencies on request. All Regional Offices have reported a variety of activities to provide outreach materials to the State Agencies as well as other organizations requesting information and materials.

Sharing of information and materials between the Health Care Financing Administration (HCFA), SSA, and AoA at the Regional, State and local levels is reflected in the Regional Office reports for the first six months of Fiscal Year 1989.

Question. How many low-income elderly persons simply didn't apply for SSI or food stamp benefits due to the lack of knowledge that they are available?

Answer. The Administration on Aging has participated as a member of the Technical Advisory Committee of the American Association of Retired Persons' (AARP) SSI Outreach Demonstration and served as a liaison to the State Agencies. Successful demonstrations in Pittsburgh, Pennsylvania, El Paso, Texas and Oklahoma City, Oklahoma resulted in a 98% increase in applications and a 57% increase in awards in the demonstration cities. This data does not provide any conclusive evidence about how lack of knowledge might affect applications for benefits such as SSI but does suggest that outreach is an effective method for increasing participation. The AARP project has been expanded for 1989. The Administration on Aging will continue to provide liaison to the States.

Question. What portion knows about their eligibility, but fail to apply due to the stigma associated with "being on welfare"?

Answer. At the present time, the Administration on Aging does not have data available that would allow us to derive any firm conclusions about the number of eligible older persons, if any, who fail to apply for benefits due to some supposed "welfare stigma", or the proportion such older persons might comprise of the universe of non-applicants. The Administration on Aging is supporting a concerted outreach program designed to reach eligible, non-participating older persons. This effort continues to emphasize that eligible persons are entitled to benefits under the SSI, Medicaid and the Food Stamp programs and that these benefits are in no way to be considered "charity" or "handouts". The Administration on Aging's outreach to eligible older persons is an on-going element of the agency's efforts to strengthen community service systems and make them responsive to the needs of older persons.

TITLE III TRANSFERS

Question. In recent years, states have increasingly transferred funds from their allotments for congregate nutrition services to the home-delivered nutrition and supportive services program. Do you perceive that states are witnessing greater need for funding for home-delivered meals and supportive services relative to the need for congregate nutrition services?

Answer. Increased use of the transfer provisions of Title III reflects the commitment of AoA and the State and area agencies on aging to the reduction of dependency among older persons and to the provision of services designed to enable older individuals to remain in their homes for as long as possible. Both

home-delivered meals and supportive services provided in the home contribute directly to the achievement of these objectives.

Question. How do you explain these transfers?

Answer. In recent years, the transfers from the congregate nutrition allotment to home-delivered meals and supportive services allotments are in response to the growing number of frail elderly persons who need special assistance to avoid institutionalization. States have placed emphasis on targeting resources to that population. This supports a major AoA objective of assisting older persons to remain independent and in their own homes as long as possible, thus reducing dependency.

CHILD ABUSE PREVENTION

Question. Estimates project that child abuse reports will rise by 500,000 from FY 1988 to FY 1990. In 1987 alone, 1,181 children died as a result of abuse and neglect. How do you propose to meet the increased demand for services when you are not requesting any increases in funding for the programs that deal with child abuse, neglect and exploitation?

Answer. Child abuse and neglect prevention and services programs are primarily the responsibility of the States. The Federal funds appropriated for Public Law 100-294 ,the Child Abuse Prevention and Treatment Act, are not intended to be the major source of funds for the delivery of ongoing child protective services. These funds are to assist State public and private agencies and organizations to address child abuse and neglect program needs; they are also used for research and demonstration of key issues which are of concern to the field as well as for training, technical assistance, resource centers, a national clearinghouse and the State grant programs in child abuse and neglect, medical neglect of disabled infants, and child sexual abuse under the the Children's Justice Act. An additional appropriation funds the State Challenge grant program for prevention of child abuse and neglect. Over the years, all of these funds have helped to stimulate the definition of critical issues, the development of solution to these issues, and have assisted States in making use of these solutions to improve their capacities to respond to the needs of abused, neglect and other high risk children and their families.

Question. By proposing to eliminate the child abuse challenge grants program, are you penalizing States that may still need Federal funds to assure adequate delivery of child abuse and neglect services?

Answer. The purpose of the Challenge Grant legislation was to encourage States to establish and maintain State Children's Trust Funds or other funding mechanisms to support child abuse prevention activities. Congress clearly recognized that ongoing prevention is a State responsibility and intended the Challenge Grants to stimulate state resources. Forty-five States have met the requirements for receiving Challenge Grant funds, and we anticipate that almost all States will have trust funds or other

funding mechanisms for child abuse prevention activities in place by the end of 1990. We are greatly encouraged by the States' response to the Challenge Grant program and believe that the legislation has achieved its purpose.

FAMILY VIOLENCE PREVENTION

Question. The 1988 reauthorization of the Family Violence Prevention and Services Act called for a new grant program and a family member abuse information and documentation project. How do you propose to fund these new activities without increasing the appropriation level over the $8,219,000 provided last year?

Answer. The Department will implement the two new provisions of the Act within current appropriation levels.

Section 311(b)(2) authorizes a new program to make grants or contracts to local law enforcement agencies. The Secretary of Health and Human Services is required to delegate and transfer funds to the Attorney General to carry out the provisions of Section 311.

Section 313 requires the Secretary to develop data on individual characteristics relating to family violence and provide for the objective documentation of data on victims of family violence and their dependents. We are working with the Public Health Service, the National Institutes of Health, the Centers for Disease Control, the Department of Justice, and other agencies to identify current info mation collection and documentation efforts in order to avoid duplication of effort.

We are developing an Interagency Agreement to transfer funds to the Department of Justice to carry out both new activities.

SOCIAL SERVICES BLOCK GRANT

The FY 1990 request for the Social Services Block Grant (SSBG) is $2.7 billion, the same level of funding requested in FY 1989. This block grant replaced the categorical grants for social services, child day care, and State and local training and retraining.

Question. Realizing that this grant gives a great deal of flexibility to the States, has the Department monitored or audited how the States have spent these monies?

Answer. The Department monitors each State's pre-expenditure report and post-expenditure report. The pre-expenditure report must meet statutory requirements before grant funds are released. Also , a summary of information in pre-expenditure reports is prepared annually which gives an overall picture of the variety of services being offered.

Under the Single Audit Act, States must conduct an independent audit of Federal programs annually. This audit must be conducted in accordance with the Comptroller General's standards for audits of governmental organizations, programs, activities, and

functions, and submitted to the State legislature and to HHS within 30 days after completion. Finally, as several GAO reports have concluded, accountability under the block grants lies primarily with the citizens of the State. Increased public oversight of all block grant programs has occurred, including the involvement of State legislatures.

Question. Don't you think the States should be required to annually report how much is spent on each major category of services, such as child care, and elderly nutrition services?

Answer. New data collection requirements were enacted by Section 607 of P. L. 100-485, the Family Support Act of 1988. States must now report annually rather than biennially: (1) the number of children and adults served and the services provided; (2) the amount spent per child and per adult, in providing each type of service; (3) the criteria applied in determining eligibility for services; and (4) the methods by which services are provided, showing separately the services provided by public and by private agencies. HHS is developing uniform definitions of services and will publish regulations to implement these requirements.

HEAD START--LOW-INCOME

Question. The proposed Head Start increase is intended to expand enrollment to 4 year old children who meet the program's low-income requirements. The proposal estimates that up to 95,000 more 4 year old children could be served with the increased funding, for a total of 547,000 children. Since children from the ages 3 to 5 years are eligible for Head Start, why expand enrollment only to 4 year old children?

Answer. President Bush has committed his administration to a goal of providing Head Start services to every eligible and interested low-income four year old in the country. The purpose in focusing on children at age four is that, as most children in this country enter kindergarten at age 5, serving a child in Head Start at age 4, or the year immediately prior to kindergarten, will have the greatest beneficial impact on preparing that child for public school.

Question. Does the proposal assume that these children will be served for one year or for 2 or more years?

Answer. As most of these children will be attending kindergarten the following year, they would be receiving one year of Head Start services.

Question. What percent of eligible children are served by Head Start in FY 1989 and what percentage would be served with the proposed increase?

Answer. There are currently an estimated 903,000 low-income children in the United States who will be entering kindergarten this fall. Currently, Head Start provides services to approximately 303,000, or 34%, of these children. With an

additional 95,000 four-year old children enrolled in Head Start, the program would provide 398,000, or 44%, of these low-income children with a Head Start experience before they begin school.

HEAD START AS DAY CARE

Question. Given that about 80% of all Head Start programs are part-day programs, how does Head Start help poor families meet their child care needs as suggested in the budget recommendations submitted by President Bush?

Answer. Although the provision of child care services is not the primary goal of Head Start (Head Start is a comprehensive child development program), we recognize it as an important need for many of the families Head Start serves. As you indicate in your question, a significant number of Head Start programs do provide full-day services directly with other Federal funds. Other agencies which operate Head Start programs obtain funding from other sources to provide child care services after the Head Start day ends. We are actively encouraging all of our grantees to explore ways they can participate in such jointly funded programs and use their Head Start program as a base on which they can "wrap around" additional child care services.

Question. What is being done to coordinate the Head Start program with other preschool or child care programs being offered by the states?

Answer: Through our regional offices, we are initiating contact with State governments to improve coordination. In the nearly 30 States that have already passed preschool programs, we are seeking to coordinate the implementation of these programs with existing Head Start programs. In other States, which may be considering launching new programs, we wish to offer the lessons learned through Head Start's experience and explain the benefits of comprehensive programs that stress parent involvement. We have also completed a national study on the relationship of State preschool programs to Head Start called, The Challenge of Coordination. Copies of the report have been sent to all Head Start programs to help them better understand the opportunities and problems that may arise in working with these new State programs. Additional guidance on how to design and operate jointly funded programs is being prepared.

HEAD START TRAINING AND TECHNICAL ASSISTANCE

Question. How much of the proposed Head Start increase, if any, will be available for training and technical assistance?

Answer. No specific dollar amount of the proposed Head Start increase has been identified for training and technical assistance since the proposed increase is requested for serving additional children. However, individual grantees may use a portion of the expansion funds they receive to train new staff or to obtain needed technical assistance.

Question. What kinds of training and technical assistance

activities were provided by the central and regional Head Start offices last year?

Answer. A large percentage of the training and technical assistance money that was not provided directly to Head Start grantees was used to fund ten Head Start Resource Centers located throughout the country. The Resource Centers provide training and technical assistance in a variety of program areas such as early childhood education, program management and family support services to Head Start programs within the region or regions that they are funded to serve. Special training and technical assistance to help programs meet the needs of handicapped children was provided through a network of contractors called Resource Access Projects (RAPs). Training and technical assistance funds were also awarded to the National Association for the Education of Young Children (NAEYC) to support the Child Development Associate (CDA) credentialing process for staff such as classroom teachers and home visitors that work directly with young children. Other funds were used for special projects such as obtaining information on publicly funded pre-school activities in various States, developing a manual to assist all Head Start grantees in developing a community needs assessment, developing a new instrument to be used by Federal staff when conducting on-site reviews of Head Start grantees, and developing a manual to assist grantees in their efforts to use volunteers in a variety of program activities.

Question. What has the effect been of relying more on individual Head Start grantees to arrange for training and technical assistance?

Answer. Local Head Start programs have used more than half of the training and technical assistance funds awarded to them to provide training that enables staff that are working directly with children to obtain a Child Development Associate (CDA) credential. Over 1,000 CDAs have been awarded to Head Start staff during the first half of this fiscal year, which is significantly more than in past years. Direct funded dollars have also enabled programs to send staff in larger numbers than in the past to training provided at the state, regional and national level. In addition, programs have pooled funds to coordinate training efforts with neighboring grantees in order to provide training that would not be affordable to individual programs.

HEAD START VS EARLY CHILDHOOD DEVELOPMENT

Question. What has the impact been on Head Start programs of the increasing number of State-funded early childhood development programs?

Answer. Head Start programs in a number of States have been involved in the development and implementation of new State-funded programs. Some Head Start programs receive State funds to serve additional children. Head Start grantees have participated on various advisory boards and attempted to promote the Head Start model of comprehensive child development services. We believe there is a need for coordination on operational issues, if we are

to avoid unproductive competition for staff, facilities and children. Head Start has begun to address these issues.

Question. For example, have Head Start programs experienced any increased competition for teachers or classroom space?

Answer. In some communities there has been increased competition for teachers with qualifications in early childhood development, especially where new State-funded programs pay higher wages than the local Head Start programs. In some areas there is also a shortage of facilities which has led to competition. For example, we know of cases where Head Start programs have lost the use of space in public schools because the school has instituted new pre-school programs and reclaimed its donated space.

Question. How is Head Start being coordinated with the new federally funded Comprehensive Child Development Centers (CCDC) program?

Answer. The Federal Head Start Bureau is managing the CCDC program and this is helping to ensure needed coordination. Head Start grantees are eligible to become CCDC grantees. In the first phase of CCDC activity, Head Start programs were awarded 16 of 30 planning grants through a competitive process. It is likely that some of the CCDC operational grants that will be awarded later this year will also go to Head Start programs. In other cases, Head Start grantees may serve as early intervention centers for agencies that will operate CCDC programs.

ADMINISTRATION ON AGING TITLE VI GRANTS TO INDIAN TRIBES

Question. I understand that the number of Indian tribal organizations receiving Older Americans Act assistance in Fiscal Year 1989 will potentially increase to 188 from the 136 that were funded in Fiscal Year 1988, despite the increase in the appropriation.

How do you account for the increased number of potential tribal organization grantees?

Answer. The increase in the number of potential Federally-recognized tribes can be attributed to applicants that fall into the following four categories: (1) those tribes that became eligible as a direct result of the 1987 amendments lowering the number of older Indians from 60 to 50; (2) those Title VI consortiums that split and made separate applications as a result of lowering the eligible number from 60 to 50 older Indians; (3) those tribes that recently received Federal recognition; and (4) those tribes that had not previously made application for various other reasons.

Question: How many tribal organizations will potentially lose funds under title VI of the Older Americans Act in fiscal year 1989?

Answer. The Administration on Aging has just completed the Fiscal Year 1989 award process and it will be several weeks before

information can be provided at this level of detail. However, those tribes that were funded above the minimum Fiscal Year 1988 award of $38,000 will experience a reduction between 32% and 47% for Fiscal Year 1989. We will forward a complete list as soon as it is completed.

Question: What is the average amount of funding decreases for tribal organizations, and why is there no supplemental request?

Answer. Existing grantees that were funded above the minimum Fiscal Year 1988 award of $38,000 will experience a reduction between 32% and 47% for Fiscal Year 1989. The Administration on Aging has not requested supplemental funding because existing funded tribes will receive technical assistance and training to enable them to coordinate the provision of Title VI services with those services provided under Title III of the Act and those resources available from other Federal programs.

NATIVE AMERICAN PROGRAMS

Question. How have increases in the number of eligible tribes and individuals impacted on the amount of funding available and the quality of services offered?

Answer. The legislative mandate of the Administration for Native Americans (ANA) is to to serve all Tribes and Native American organizations. All Tribes have been eligible for ANA funds since the passage of the Native American Programs Act of 1974. ANA provides assistance to organizations only, and does not make grants to individuals.

The Administrative for Native Americans has taken a number of specific steps to maximize the use of available funds and maintain the quality of services provided to our program constituency. We have entered into a series of agreements with other Federal agencies to make their resources available to Native American organizations; we have provided technical assistance to applicants in leveraging other resources including those from the private sector; and, as part of our competitive funding process, we require applicants to identify non-ANA resources they will utilize for their projects.

Question. How many site visits were made in FY 1987, 1988, and 1989 for technical assistance or to monitor federal grant dollars?

Answer. During FY 1987 ANA staff conducted 36 monitoring site visits. To supplement staff efforts, approximately 150 technical assistance visits were provided by ANA funded resources. In FY 1988, staff conducted 21 monitoring visits and ANA funds were used to provide approximately 150 technical assistance visits on site. In FY 1989 to date, staff have conducted 3 monitoring visits, and ANA funds paid for 43 technical assistance visits.

Question. What is the budgeted amount in fiscal 1990 for this purpose, and how many site visits are planned?

Answer. Because specific budget plans for this purpose have not yet been developed for FY 1990, the number of site visits by ANA staff has not been established.

Question. Have the programs administered by the Administration for Native Americans made a difference, or are there still substantial unmet need? Be specific.

Answer. Programmatic activities provided by the Administration for Native Americans have had a positive impact on Native American Tribes and organizations in strengthening their efforts toward self-sufficiency. The Administration for Native Americans has provided financial support and technical assistance for a wide range of social and economic projects as well as for activities to improve the governance capabilities of Native American communities.

During fiscal years 1987 and 1988, ANA funded projects resulting in more than 25,000 jobs for Native Americans. During the same two years, ANA funded projects for social and economic strategies which created or expanded over 420 businesses owned and operated by Native Americans. In addition, ANA funded governance activities strengthening Tribal governments and encouraging outside investments in Tribal development projects.

Many concerns remain in Native American communities which must continue to be addressed. Native Americans experience more poverty, higher unemployment, a higher rate of suicide, a higher rate of children in out-of-home placement, and poorer health than other Americans. The Administration for Native Americans is the only agency with the legislative authority to address the concerns of all Native American communities, including Native Hawaiians and Alaska Natives.

WHITE HOUSE CONFERENCE ON AGING

Question. The 1987 Amendments to the Older Americans Act require the President to call a White House Conference on Aging in 1991. What planning activities do you anticipate will be accomplished in fiscal 1990?

Answer. Title II of the Older Americans Act Amendments of 1987 authorizes the President to call and the Secretary of Health and Human Services to plan and conduct a White House Conference on Aging in 1991. At the present time the Department of Health and Human Services is investigating a number of alternative strategies for conducting a White House Conference. No final decisions have been made at this point. However, we expect to resolve all outstanding issues within a short time and will keep Congress fully informed on our progress, including plans for any activities identified for implementation in Fiscal Year 1990.

Question. Your budget does not appear to request funds for planning activities for the [White House] conference [on aging]. What, if any, level of appropriations might be necessary during fiscal 1990?

Answer. No decisions have been made at this time about

whether funds will be needed during Fiscal Year 1990 for activities related to a 1991 White House Conference on Aging and, if so, what level of funding would be required.

DATA COLLECTION

Question. The 1987 amendments to the Older Americans Act required improved data collection on recipients of supportive and nutrition services as well as expenditures on services beginning in fiscal year 1989.

What is the status of your efforts on this task?

Answer. The Older Americans Act Amendments of 1987 added significant new data-gathering and reporting requirements to Sections 202 and 207 of the Act. Specifically, Section 202(a)(19) of the Act requires AoA to collect specific statistical data relating to programs and activities carried out with funds provided under Title III of the Act. Section 207(a)(4) requires AoA to include in its annual report to Congress statistical data and an analysis of information regarding the effectiveness of State and Area Agencies on Aging in targeting services to older individuals with the greatest economic or social needs, with particular attention to certain special populations, including low-income minority individuals and other low-income persons. In order to obtain the necessary data to comply with this statutory requirement, the Administration on Aging developed and issued to the States a new OMB-approved State Program Report form which the State Agencies on Aging will utilize to collect and report these program data beginning with Fiscal Year 1989.

OLDER AMERICANS ACT STUDY OF UNMET NEED

Question. The 1987 amendments to the Older Americans Act required you to complete a study by September 1989 on the unmet need for supportive and nutrition services and senior centers. Do you expect that you will have any preliminary information that would be useful to the Subcommittee as it makes deliberations on the level of funding for these programs for fiscal 1990?

Answer. By June 30, 1989, the Administration on Aging will receive information from States on their studies of unmet need. We do not expect to have completed our analysis of the information from the States until September. It is unlikely that information will be available in a useful format in time for deliberations related to the Fiscal Year 1990 budget.

RETURN ON FEDERAL INVESTMENT

Question. Your budget document estimates that the Administration on Aging investment per meal on a dollar basis will decrease from $1.65 in 1988 to $1.60 in 1990. How do you account for this?

Answer. The budget estimates are based on the assumption that the return on Federal investment--what the Federal government has to invest to produce a meal--will continue to improve as in past

years. For example, the return on federal investment for Fiscal Year 1987 was $1.66 and in Fiscal Year 1988 it decreased to $1.63. We attribute the anticipated FY 1989 decrease in the return on Federal investment to increased voluntary contributions and improved program efficiency.

Question. Could you explain how you calculate the Federal investment in the nutrition program?

Answer. The Return on Federal Investment is the level of Federal funds that has to be invested to produce a meal. To calculate the Return on Federal Investment, the Title III-C funds available for meals after transfers are divided by the total number of meals served.

FOR EXAMPLE: Fiscal Year 1987 Return on Investment

Funds available for Meals after Transfers	$386,426,635
Number of meals served	232,623,720

Equals Fiscal Year 1987 Return on Federal Investment $1.66 (rounded)

CONSOLIDATION OF RESEARCH AND DEMONSTRATIONS

Question. What benefit is there in consolidating your request for AOA's training, research, and demonstration activities with other research and demonstration authorities administered within the Office of Human Development Services?

Answer. The request for combined research and demonstration line-item in the budget is a display only. It is intended to emphasize the total research and demonstration effort within the Office of Human Development Services.

Question. Would there be any difference in how these various authorities are administered?

Answer. There will be no change in how these authorities are administered. The consolidated budget request is for display purposes only.

ADMINISTRATION ON AGING

Question. In 1987, the Older Americans Act was amended to require that the Commissioner on Aging report directly to the Secretary of Health and Human Services. What actions, if any, have been taken to change this reporting relationship?

Answer. The Department of Health and Human Services has taken the necessary steps to carry out all provisions of the Older Americans Act Amendments of 1987. On January 2, 1988, the former Secretary of the Department issued a memorandum to all operating and staff divisions directing the Commissioner on Aging to report directly to the Secretary to ensure that concerns of Older Americans are considered fully in various policy matters addressed by the Department.

In addition, several Federal Register announcements have been published under the signatures of the Commissioner and the Secretary rather than the Assistant Secretary. The Administration on Aging no longer participates in the Coordinated Discretionary Program administered by the Office of Human Development Services. This means that the Commissioner has total decision-making authority over Aging research and demonstration activities.

Question. What has been the result of the study undertaken by the Assistant Secretary for Management and Budget to examine and make recommendations on organizational and support matters raised by the law change?

Answer. The Assistant Secretary for Management and Budget procured a contract with Macro Systems, Inc. to examine the organizational and support matters concerning the Administration on Aging raised by the recent amendments. That study is currently under review within the Office of the Secretary.

Question. Do you believe that appropriations for the Administration on Aging should be separated out from those of the Office of Human Development Services to clarify the budget relationship between AOA and OHDS in view of the 1987 law change?

Answer. There is no need to separate the appropriations for the Administration on Aging. There are other organizations with different reporting requirements that are included in the Human Development Services appropriation, such as the President's Committee on Mental Retardation and the Federal Council on Aging.

Question. What is the current staffing level for AOA?

Answer. The current authorized staffing level is 165 full-time equivalents. There are currently 160 persons on-board against that ceiling.

Question. Do you believe that the current staff level is sufficient to carry out AOA's responsibilities?

Answer. Yes, the current staff level is sufficient to carry out the responsibilities under the law.

CHILD DEVELOPMENT CENTERS

Question. Why are you proposing that this program be administered under Section 1110 of the Social Security Act (relating to cooperative research and demonstration projects to decrease dependency and aid in coordination and planning between public or private welfare agencies)?

Answer. The Section 1110 authority is a broader authority which will allow the same activities to be carried out while reducing the number of separate new categorical programs.

CHILD WELFARE SERVICES

Question. Will your proposal to eliminate discretionary funding for temporary child care and handicapped nurseries and to

provide funding for this activity under the authority of the child welfare research and demonstration program (for which you are not requesting discretionary funding) assure the same level of funding for this activity in the future? If so, how?

Answer. The Secretary currently has the authority to operate temporary child care and crisis nurseries activities under Section 426 of the Social Security Act (SSA). In FY 1990, the Secretary will continue to fund similar demonstration projects under the child welfare research and demonstration program. An amount equal to the FY 1989 appropriation for Temporary Child Care and Crisis Nurseries was added to the FY 1990 budget request for the child welfare research, training or demonstration projects program (Section 426, Title IV-B of the SSA) for this purpose.

Question. Why aren't you requesting funding for the demonstration projects relating to developing alternative care arrangements for infants who remain hospitalized inappropriately (border babies) authorized under the child welfare research and demonstration program?

Answer. The Department is requesting funding under several different authorities which not only address the issue of providing appropriate care for babies abandoned by parents in the hospital, but also the overall issue of caring for children born with AIDS and drug dependencies.

In FY 1989, the Office of Human Development Services is providing approximately $2.8 million to fund a wide range of demonstration projects that offer models for providing social services to HIV-infected children and their families. This office expects to fund pediatric AIDS projects at the same level in 1990 as in 1989 with the Child Welfare Research and Demonstration, Head Start, Developmental Disabilities and Administration on Native Americans funds. Projects include:

- o recruiting and supporting foster families, coordinating medical and social services, and providing innovative child welfare services appropriate for infants and young children who have tested positive for AIDS, and whose parents are unable to care for them. Both foster family care and innovative community-based alternatives to hospitalization are being considered for project awards ($1.3 million);

- o developing guidelines for developmental services, and legal rights and protection and advocacy policies for HIV-infected children and their families ($0.3 million).

Question. Under your proposal to combine these programs, what would prevent States from using less of the child welfare services funds for direct services and, instead, diverting the funds for increased administrative costs of the other programs?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

Question. How much do you anticipate funding under the child welfare services program would be reduced (state by state) if, as you are proposing, states could no longer transfer funds from their Title IV-E foster care program to child welfare services?

Answer. We expect that there would be a very small reduction. Last year, States transferred only $5.1 million.

INDEPENDENT LIVING SERVICES

Question. How do you anticipate States could provide Independent Living services (currently authorized under the Title IV-E program) as part of Child Welfare Services, as you propose, without reducing the provision of other services?

Answer. The decision would be left to the States on how to divide the funds and how much to spend on each activity. In addition, the States have always been able to use Title IV-B funds for Independent Living activities.

RESEARCH AND DEMONSTRATION

Question. Why aren't you requesting discretionary funding for the child welfare research and demonstration or training programs?

Answer. We are requesting funds for Child Welfare Research and Demonstration. The amount requested is $12,355,000. An additional $3,696,000 is requested for child welfare training.

Question. How would these funds be administered under your request to combine human services research, training, and demonstrations?

Answer. These programs have been combined for display purposes only. They will be administered as separate categorical programs for their authorized purposes.

CHILD WELFARE SERVICES PROGRAM

Question. The Child Welfare Services program is designed to help State public welfare agencies achieve the goal of keeping families together. State services include: preventive intervention; counseling; and when necessary, services to develop alternative placements like foster care or adoption. What are the latest available data on the services provided and the characteristics of recipients under the child welfare services program?

Answer. States are not required to submit detailed information on the use of title IV-B funds. A survey of the latest Title IV-B State Plans indicates that the following are the more commonly offered services to prevent unnecessary placement and to assist in permanancy planning for children: information and referral; diagnosis and evaluation; homemaker; child day care; crisis counseling; respite care; sexual abuse counseling; employment services; health services; emergency financial assistance; transportation; and emergency shelter care.

We do not have information on the characteristics of the recipients of these services.

Question. How will your proposal to combine the existing child welfare services program with the administration and training authorities of both the foster care and adoption assistance programs improve the delivery of child welfare services?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

Question. What would be the funding for the child welfare services component under your proposed combined program?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

FOSTER CARE PROTECTION

Question. Why are you proposing to reduce states' requirements regarding implementation of foster care protections for funding eligibility under the child welfare services program?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

Question. Do you anticipate that claims under the adoption assistance program will continue to increase?

Answer. Yes, for the foreseeable future. Children continue as beneficiaries for an extended period of time, generally, until they are age 18. Until the number of children exiting from Adoption Assistance is equal to the number entering, the caseload will grow.

ONE-TIME EXPENSES

Question. How will providing an income tax deduction for the one-time expenses of adopting children with special needs, as you have proposed, impact on the use of the one-time adoption assistance payments and payments for maintenance costs under the adoption assistance program?

Answer. It should not impact on them. However, some families seeking to adopt special needs children might be faced with enormous costs before adoption, higher than the limit under the non-recurring costs reimbursable under Title IV-E Adoption Assistance. For them the tax deduction might enable them to adopt a child they otherwise could not adopt.

SPECIAL NEEDS CHILDREN

Question. Do you anticipate that more special needs children will be adopted, and, if so, more children will be eligible for payments for maintenance costs?

Answer. Yes, we expect more children to be adopted and eligible for payments under Title IV-E Adoption Assistance.

FOSTER CARE POPULATION

Question. Can you explain why the number of children in foster care has increased markedly since fiscal year 1980?

Answer. A major component of the increase in the number of IV-E children is due to noncomparable figures resulting from improved State reporting of average monthly number of children since 1988. Since 1988 the annual increase has been and is estimated to continue to be about one percent. In addition, the presenting problems of drugs, AIDS, and increased reporting of child abuse and neglect cases have increased the number of children in foster care. Finally, States have begun to claim a greater proportion of their children who are eligible for IV-E foster Care.

Question. How do you anticipate reductions in States' funding for child welfare services -- through your proposal to eliminate the transfer of funds from Title IV-E to child welfare services as well as the proposal to provide independent living services with existing child welfare services money -- will affect foster care populations?

Answer. We think the provision of services would continue at about the same level.

Question. Do you anticipate the number of children in AFDC foster care and the claims for foster care expenditures will continue to increase?

Answer. Yes, we think that the caseload will continue to increase. Also, many States periodically increase rates paid to foster parents and this will increase amounts claimed.

MERGING OF CHILDREN'S PROGRAMS

Question. You have proposed combining appropriations for the administration of the foster care and adoption assistance programs. What impact would merging these appropriations into one State grant have on program operations?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

TRANSITION PERIOD

Question. How will states provide services for children making the transition from the foster care program to independent living if the separate authority and funding for the independent living program is eliminated as you propose?

Answer. The legislation to combine these programs, proposed by the Reagan Administration, is currently under review by the Bush Administration.

HEAD START REGULATIONS

Question. The December 8, 1988, proposed Head Start regulations would require Head Start programs to meet a variety of new requirements related to minimum days and hours of operation, limits on class sizes, minimum number of home visits, staff qualifications, and state and local licensing standards. The regulation estimates that these changes will cost the program $15 million and that the cost increases can be accommodated in current budget policy. Will increased funding be available to the programs?

Answer. We hope to continue to make increased funding available to programs to help them meet proposed requirements to provide more contact time and reduce class sizes in order to improve program quality. When the proposed regulations in this area were being developed in 1987, we estimated that the costs associated with making the proposed changes was $35.8 million. During fiscal years 1987 and 1988, we awarded $20.8 million in increased funds to selected programs to increase contact time and reduce class sizes, reducing the amount needed to $15 million. In FY 1989 we expect to award approximately $5.6 million more, leaving a balance of $9.4 million. We do not expect that the final rule will become effective until the fall of 1991.

Question. Will children be dropped from the program as a result of these changes?

Answer. No children actually enrolled in the program will be dropped. We also do not expect that there will be any significant national reduction in future enrollment as a result of these changes. There may be a few individual programs whose current operations vary so significantly from the new regulations that some enrollment reductions will occur.

COMPREHENSIVE EVALUATION OF HEAD START

Question. There are currently over 1,290 grantees in the Head Start program. We understand that there have been very limited numbers of on-site evaluations of Head Start grantees. How many on-site evaluations of Head Start grantees did you perform in FY 1988 and FY 1989; and how many are projected for FY 1990?

Answer. In FY 1988, 315 on-site evaluations were reported. In FY 1989, we have completed approximately 90 reviews through April and expect to add a small additional number during the rest of the year. For FY 1990 we hope to be able to return to our traditional goal of being able to visit one-third of the programs each year and make 430 on-site assessments. It is expected that by FY 1990, a national contract will be awarded for the purpose of supplementing and enhancing the Regional Offices ability to conduct on-site monitoring of one-third of the Head Start grantees each year.

Question. Please provide information on audits for the same years.

Answer. Although no records are kept concerning the number of audits prepared each year for Head Start grantees, it is estimated that approximately three-fourths of our grantees are audited each year. Depending on the type of organization, i.e., local government, community action agency, local board of education, Head Start grantees comply with the A-128 OMB circular pertaining to the requirement for state and local agencies to have annual audits, or the A-110 OMB circular pertaining to the requirements that private, non-profit agencies have audits either annually or every other year depending upon the agency's preference.

BOARDER BABIES

Question. Last year, President Reagan signed into law the Abandoned Infants Assistance Act of 1988, which authorized $30 million to help find foster care and adoption opportunities for babies abandoned in hospitals. President Bush has stressed his support for the family, yet there is no request for this in the FY 1990 budget. Does the Administration support this initiative?

Answer. Yes, the Administration supports this initiative. While there is no specific line-item request in the Human Development Services appropriation, the Department is requesting funds under several authorities which not only address the issue of providing appropriate care for babies abandoned by parents in the hospital, but also the overall issue of caring for children born with AIDS and Drug dependencies. In 1989, the Office of Human Development Services provided under current authorities approximately $2.8 million to fund a wide range of demonstration projects that offer models for providing social services to HIV-infected children and their families. It is expected that the same amount will be made available in 1990.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

NATIONAL MINORITY ORGANIZATIONS

Question. For some time this Committee has been interested in ensuring that national organizations representing the interests of our nation's minority elderly will be supported by the Administration on Aging. It is my understanding that national contracts have now been given to national organizations representing each of the various major ethnic groups, other than Asian Americans and Pacific Islanders and that there have been problems in providing the same type of support to an organization representing this particular segment of our society. Accordingly, I would appreciate the Administration on Aging providing the Committee with a detailed report on the funding history of these various entities and a plan for also targeting this elderly population.

Answer. There are several components to be addressed in answering your question

A. Funding History

Attached is a table which outlines in detail the history of AoA funding support over the past ten years for the four national minority aging organizations referred to in the above question, including the National Pacific/Asian Resource Center on Aging (NP/ARCA). Initially, each organization received a five-year grant at levels approximating $1 million to support their core activities. With regard to the National Pacific/Asian Resource Center on Aging (NP/ARCA) and the National Indian Council on Aging (NICOA), AoA grant support has continued to underwrite essentially 100% of the staff salaries and other basic operating costs of these organizations. Over the ten-year period, 1979 to date, the amount of core grant support for NP/ARCA and NICOA has approached $2 million each.

The two other national minority aging organizations, the National Caucus and Center on Black Aged, and the Association Nacional Pro Personas Mayores, have demonstrated the capacity to move well beyond a reliance on AoA support for their organizational survival. Thus, they have been able to compete successfully for a number of AoA demonstration and training grant awards, of which several have run concurrently during the 1980's.

As the ten-year funding history will attest, AoA has an unbroken record of support to the four national minority aging organizations. There are differences in the level of funding support provided to each organization over this period, but these differences have resulted from their differing capacities to compete for and carry out projects funded under AoA's Title IV grant competitions. AoA has and will continue to be fair and evenhanded in its relationships with the four national

minority aging organizations. Nonetheless, events and circumstances during the past year, as explained below, have resulted in a change in the relationship between NP/ARCA and AoA.

B. Recent Relationships Between AoA and NP/ARCA

All four organizations had project grants scheduled to end at the end of FY 1988. Based on provisions in the Senate and House Appropriations Committees Reports accompanying the FY 1988 DHHS appropriations bill, which direct AoA to support organizations representing the interests of minority elderly, discussions between AoA staff and each organization began in the spring of 1988 on the development of new project proposals for non-competitive review and funding. Concept papers were drafted by each organization as a basis for discussions with AoA. After clarifying discussions which resulted in approvable concept papers, three of the organizations were requested by AoA to prepare draft grant applications for an internal AoA review. AoA again suggested certain revisions in the grant proposals and the amended grant applications were approved for funding beginning on September 30, 1988.

The National Pacific/Asian Resource Center did not submit a satisfactory project proposal; in fact, its general unresponsiveness raised some serious questions about the performance of NP/ARCA, about its capacity to act as an

independent operational National Center, and about its recognized stature as a visible recognized representative of the interests of Pacific Asian elderly. Thereupon AoA undertook a program review of NP/ARCA, which included site visits during the latter part of August, 1988.

A no-cost extension was requested by NP/ARCA and approved by AoA to run from September 30, 1988 to January 31, 1989. During this period AoA communicated to NP/ARCA the results of its program review of the Center. The Administration on Aging made a series of recommendations for NP/ARCA's consideration in submitting a grant application to AoA for funding in FY 1989. The recommendations were aimed at achieving a revitalization and restructuring of NP/ARCA to assure greater accountability and responsiveness to the Pacific Asian community, and at pointing the Center toward attaining the stature, visibility, and independence of a truly national minority aging organization.

The Administration on Aging recognized that NP/ARCA would need an interim planning period beyond January 31, 1989 to undertake the kinds of organizational and staffing steps which AoA was recommending to reconstitute the Center. Accordingly, a supplement of $81,325 was approved that extended the budget and project periods from February 1, 1989 to April 30, 1989.

In mid-March, NP/ARCA submitted a grant application to AoA which requested funding for a seventeen-month project period at a level of $486,859. The proposal did not adequately address the recommendations AoA made to NP/ARCA on strengthening its capacity to represent the broad interests of the Pacific Asian community. Further, the extraordinarily high budget submitted by NP/ARCA convinced AoA that its stewardship responsibilities for the Title IV program could not be met through an ordinary internal AoA review of the NP/ARCA grant application. (On an annualized basis, NP/ARCA's budget request was $344,668, almost 75% higher than the $200,000 yearly funding levels which NP/ARCA as well as the other three national minority aging organizations had been receiving in recent years).

For these reasons, AoA convened an outside review panel of private and public sector experts in the field of aging, representing perspectives both of national aging organizations and of the minority aging community. AoA is now weighing the results of the peer review and considering what next steps to take.

The Administration on Aging remains committed to Congress' interest in providing support for special representation and outreach services to those in the Pacific Asian elderly community who require such assistance. While AoA has awarded NP/ARCA almost $2 million during the past ten years, we remain concerned that NP/ARCA has not developed and matured as an organization, thereby limiting its effectiveness in representing the interests of the Pacific Asian elderly community.

Over the years, we have made special efforts to assist and nurture this organization to attain the level of capability and capacity required to meet the needs of the Pacific Asian elderly community. A great deal of financial assistance has been awarded to NP/ARCA under the most favorable options available to us

consistent with DHHS grants administration procedures, and a considerable amount of staff resources have been directed toward assisting NP/ARCA both with substantive information and with guidance concerning administrative grant procedures.

For the present, at AoA's request, NP/ARCA has submitted a three-month cost extension of $68,666 for its current grant which would extend the project period to July 31, 1989. AoA will act on this request as expeditiously as possible to minimize any disruption of NP/ARCA's project.

ADMINISTRATION ON AGING

FUNDING HISTORIES OF THE 4 NATIONAL MINORITY AGING ORGANIZATIONS
As of April 1989

ORGANIZATION	DATES	FUNDING
1. NATIONAL PACIFIC/ASIAN RESOURCE CENTER ON AGING (NP/ARCA)		
90AM2199	11/01/79 - 09/29/84	$ 907,972
90AM0105	09/30/84 - 09/29/85	199,842
90AM0157	09/30/85 - 09/29/86	156,613
90AM0253	09/30/86 - 12/31/87	200,000
90AM0294	09/30/87 - 01/31/89	199,979 &
	04/30/89	81,325
	07/31/89	68,666(pending)
	TOTAL FUNDING:	$1,814,397
2. NATIONAL INDIAN COUNCIL ON AGING (NICOA)		
90AM2192	09/28/79 - 09/30/84	$ 870,086
90AJ1025	09/30/84 - 08/31/86	199,900 &
		50,000 (HDS)
		42,280
90AJ2010	09/01/86 - 11/30/87	100,000 (AoA) &
		100,000 (ANA)
90AM0295	09/30/87 - 11/30/88	220,000
90AM0354	09/30/88 - 09/24/89	200,000
	TOTAL FUNDING	$1,632,266 (AoA)
		$ 150,000 (other OHDS)
3. ASSOCIATION NACIONAL PRO PERSONAS MAYORES		
90AM2198	11/01/79 - 05/15/84	$1,317,893
90AM0083	09/30/84 - 10/29/85	150,000
90AM0132	09/23/85 - 03/27/87	100,000
90AM0216	09/30/86 - 08/31/88	200,000

90AM0299	09/01/87 - 01/31/90	150,000
90AM0355	09/30/88 - 02/28/90	200,000
	SUBTOTAL	$2,117,893

(Funding History Table Cont.)

3. ASSOCIATION NACIONAL PRO PERSONAS MAYORES

Training Projects

90AT0142	10/01/84 - 01/31/86	$ 135,054
90AT0305	07/01/86 - 01/31/88	133,463
90AT0380	02/30/88 - 09/30/89	145,680
	SUBTOTAL	$414,197
	TOTAL FUNDING	$2,532,090

4. NATIONAL CAUCUS & CENTER ON BLACK AGED (NCBA)

90AM2197	11/01/79 - 05/15/84	$1,184,648
90AM0077	09/30/84 - 09/29/85	150,000
90AM0090	09/30/84 - 01/29/86	200,000
90AM0098	09/30/84 - 09/30/86	124,956
90AM0160	08/01/85 - 11/30/87	175,000 & 65,000 (DOL)
90AM0178	07/01/86 - 10/31/87	200,000
90AM0353	09/30/88 - 02/28/90	200,000
	SUBTOTAL	$2,234,604 (AoA) 65,000 (DOL)

Training Projects

90AT0065	03/08/81 - 02/28/84	$ 349,976 341,133 349,879
(training provided to benefit all four aging minority groups)		
90AT0133	09/30/84 - 12/30/85	200,000
90AT0199	09/30/86 - 12/31/87	150,000
90AT0353	10/01/87 - 01/31/89	150,000
	SUBTOTAL	$1,540,988
	TOTAL AoA FUNDING	$3,775,592
TOTAL AoA FUNDING FOR THE FOUR NATIONAL MINORITY AGING ORGANIZATIONS		$9,754,345

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

RUNAWAY AND HOMELESS YOUTH

Question. The Anti-Drug Abuse Act of 1988 (P.L. 100-690) extended the authorization of programs under the Runaway and Homeless Youth Act. The President's budget for FY 1990 has requested level funding for the program. Indications in Pennsylvania are that the problem of runaway and homeless youth is increasing, not stabilizing. What impact will a freeze in the program have on the number of centers supported, the level of that support and the number of youths served in FY 1990?

Answer. The number of centers funded would, in all likelihood, remain the same as in FY 1989. The level of support and the number of youth served would remain relatively constant.

Question. What mechanism does the Department use to estimate the runaway and homeless youth populations?

Answer. We have relied on the National Statistical Survey on Runaway Youth, prepared in 1975 and 1976 and, more recently, on the report entitled "Runaway and Homeless Youth - National Program Inspection", prepared by the Office of Inspector General (OIG), Department of Health and Human Services, in October, 1983.

Since the 1983 OIG report, the Department's estimate of the annual number of runaway and homeless youth has been "slightly more than one million."

Question. Please provide the most recent estimates with a State-by-State breakdown.

Answer. Our best current estimate of the number of runaway and homeless youth in America is "slightly more than one million." No State-by-State breakdown of this number exists.

RUNAWAY AND HOMELESS YOUTH PROBLEMS

Question. Is the problem increasing?

Answer. We think it is. We have had an unprecedented number of requests this year for application forms for our basic center or basic shelter program.

Question. How does the number of youth estimated to be served by the program in FY 1989 compare with the previous five fiscal years?

Answer. Please refer to the following table:

TABLE I

NUMBER OF BASIC CENTERS FUNDED AND NUMBER OF YOUTH SERVED
RUNAWAY AND HOMELESS YOUTH PROGRAM

Fiscal Year	Basic Centers	Youth Served By Centers	Youth Served By Hotline
1984	265	305,500	250,000
1985	274	341,000	260,000
1986	286	339,400	*
1987	307	340,000	280,000
1988	327	345,000 **(Estimate)	285,000 ***(Estimate)
1989	345 (Estimate)	355,000 (Estimate)	290,000 (Estimate)

* No data available.

** Voluntary reports from centers have not been collated and analyzed yet.

*** Analysis has not yet been received from contractor.

TRANSITIONAL LIVING PROGRAM

Question. Why did the Department not include funding request for the new transitional living program?

Answer. The department's action with regard to this program is consistent with the administration's policy on deficit reduction. It is our belief that these needs could be adequately met with funds under current federal authorities, e.g. Title XX, and other sources of funding within the States.

Question. If funding for the program is not provided, what incentives do providers have to provide transitional shelters?

Answer. The law offers the incentive of the free use of surplus Federal facilities as transitional living youth shelters facilities whether or not an applicant is receiving a federal grant to provide transitional living services.

THE ANTI-DRUG ABUSE ACT

Question. The Anti-Drug Abuse Act of 1988 authorized funding for two demonstration programs -- the Drug Education and Prevention Program for Runaway and Homeless Youth and the Drug Education and Prevention Program for Youth Gangs. The sum of $15 million was appropriated for each program. Has the Department proposed regulations to implement these programs?

Answer. No, regulations are not needed to implement these programs. Program announcements for these two programs were published in the Federal Register on April 14, 1989.

Question. Has the Department issued program announcements for either program?

Answer. Yes, the Department has published program announcements for both programs on April 14, 1989.

Question. When is an announcement expected?

Answer. The Announcements for the Youth Gang Drug Prevention Program and the Drug Abuse Prevention Program for Runaway and Homeless Youth were published in the Federal Register on April 14, 1989.

Question. Does the Department expect to fund demonstration projects in FY 1989 under these programs? If so, when.

Answer. Yes, the Department expects to fund demonstration projects under both announcements in September, 1989.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

JUVENILE JUSTICE ALLIANCE

Question. The Juvenile Justice Alliance (JJA) is an organization that is a private, non-profit, coalition in Oregon of public agencies and youth development organizations that has demonstrated through a three year demonstration project that traditional youth serving agencies are willing to provide remediation services to youths in the juvenile justice system. I share the JJS's desire to bring this project to a national scale, involving federal agencies and youth development organizations in a partnership to serve at risk youth. This would begin with a three year, six state demonstration project replicating what was accomplished in Oregon; allowing at risk youth to participate with those in the private youth development organizations on projects at work sites provided by land and resource management agencies. In correspondence with Secretary Bowen of Augustl, 1989, I learned of his support for the Juvenile Justice Alliance proposal and was advised of the work underway to obtain a Memorandum of Understanding with the Departments of Justice, Interior and Agriculture to begin national participation in the project. I understand that the interagency agreements to enable the JJA project to move forward are now in place. Please advise me of this initiative.

Answer. A Memorandum of Understanding (MOU) has been developed among the Administration for Children, Youth and Families (ACYF) and the Administration of Native Americans (ANA) of the Department of Health and Human Services, the Office of Juvenile Justice and Delinquency Prevention of the Department of Justice, the Bureau of Land Management of the Department of Interior and the Forest Service of the Department of Agriculture. This MOU provides a framework to assist in the development and

implementation of a three year, six State (Oregon, California, Washington, Nevada, Utah and Idaho) demonstration that replicates and tests specific strategies having national implications. Currently, ACYF and ANA have signed the MOU. It is being reviewed by the other agencies and should be completed in the near future.

Question. What funding is required to further this project?

Answer. It is estimated that funding for this project will be several hundred thousand dollars.

Question. Is that funding available aud is there any commitment from the private sector to participate in the funding?

Answer: None of the funding will be provided through the Department of Health and Human Services. The Director of JJA is currently negotiating with a number of private organizations for funding. It is anticipated that funding through the private sector will eventually be secured.

Question. Assuming the demonstration project is a success, will there be any efforts to assess the support of the private youth development agencies for a full scale national partnership?

Answer. There are currently no plans for such an assessment.

Question. What other types of initiatives exist joining the Federal government and the private sector to address the needs of at risk youth?

Answer. In FY 1986, with the Department of Justice as the lead agency, the Department of Health and Human Services joined with the Department of Labor and the Department of Education in support of Cities in Schools. Inc. Cities in Schools is a private, non-profit organization whose objectives are to promote and facilitate the coordinated delivery of existing health, social, education, and other supportive services at educational sites for the benefit of at-risk youth and their families.

Cities in Schools is now operating in thirty cities and one hundred thirty educational sites. Thirty-three additional cities are in the process of exploring and/or initiating the Cities in Schools program.

Question. Do you believe there is promise in bringing these two initiatives together?

Answer. Whether there is promise in bringing there two entities together will be, to a large extent, indicated by the success of this initiative.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until tomorrow morning at 9:30 a.m.

[Whereupon, at 4:10 p.m., Thursday, April 13, the subcommittee was recessed, to reconvene at 9:30 a.m., Friday, April 14.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

FRIDAY, APRIL 14, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:08 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Byrd, Bumpers, and Stevens.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

STATEMENT OF JAMES F. DICKSON III, M.D., ACTING ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

GARY R. NOBLE, M.D., DEPUTY DIRECTOR (HIV), CENTERS FOR DISEASE CONTROL

ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH

W. HARELL LITTLE, DIRECTOR, DIVISION OF PUBLIC HEALTH SERVICE BUDGET

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

FREDERICK K. GOODWIN, M.D., ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

JAMES R. ALLEN, M.D., M.P.H., ACTING DIRECTOR, NATIONAL AIDS PROGRAM OFFICE

OPENING REMARKS

Senator HARKIN. The subcommittee will come to order.

This morning the subcommittee will examine the budget request for the Office of the Assistant Secretary for Health and the Centers for Disease Control.

Once again, the administration has requested that we consolidate the AIDS budget into a single account in the Office of the Assistant Secretary for Health. Congress has not agreed to this proposal in the past. We will, however, take this opportunity to examine the AIDS budget this morning.

With all the AIDS activities consolidated in the Office of the Assistant Secretary for Health, the total request for fiscal year 1990 is $1.949 billion. The AIDS request is for $1.6 billion, an increase of $310.8 million, or 24 percent. The non-AIDS portion of the request is for $348.8 million, an increase of $44.5 million, or 14.6 percent.

I am also looking forward to learning more about plans for a medical treatment effectiveness initiative. The administration has requested $52 million to study treatments that lead to effective outcomes, an increase of $46 million over funding for this activity last year. Keeping the patient in mind, I want to make sure we are encouraging treatments that are effective and necessary. Keeping the taxpayer in mind, I want to learn how and if the Department actually plans to use this information to encourage medically effective treatments.

With an eye to the budget deficit and the untenable rise in the cost of health care, I need to make sure that the effectiveness initiative is a success so that it will lead to useful practice guidelines for health care providers and bring about more prudent spending for health services.

We are pleased to have Dr. James Dickson, the Acting Assistant Secretary for Health, with us today. Dr. Dickson, we will put your entire statement in the record and would ask you to summarize it briefly. I know you are accompanied by senior officials from the National Institutes of Health, the Centers for Disease Control, Health Resources and Services Administration, and the Alcohol, Drug Abuse, and Mental Health Administration who are experts in the AIDS activities. We look forward to receiving an update from you and your associates on AIDS.

PREPARED STATEMENT

At this point, I leave the record open for any opening statements by Senator Specter or any of my colleagues on the subcommittee.

So, Dr. Dickson, again, welcome to the subcommittee and please proceed with the summary of your remarks which I understand will basically focus on AIDS. Your complete statement will be included in the record.

[The statement follows:]

STATEMENT OF DR. JAMES F. DICKSON, III

I appreciate the opportunity to appear here today to discuss the FY 1990 budget request for the appropriations in the Office of the Assistant Secretary for Health (OASH) -- The National Human Immunodeficiency Virus Program request of $1.6 billion, the Medical Treatment Effectiveness request of $52 million, the Public Health Service (PHS) Management request of $190 million, and the Retirement Pay and Medical Benefits for Commissioned Officers request of $110 million. Except for the National Human Immunodeficiency Virus Program and the Adolescent Family Life Program, the FY 1990 OASH budgets are included in the Bush Budget residual freeze category. In general, the funding levels addressed today were proposed in the FY 1990 Reagan budget.

NATIONAL HUMAN IMMUNODEFICIENCY VIRUS (HIV) EPIDEMIC

As you well know, Mr. Chairman, AIDS is our number one public health priority. In the Public Health Service (PHS), the battle against the HIV epidemic has engaged all relevant operating agencies with coordination through the National AIDS Program Office in my Office and through the Public Health Executive Task Force on AIDS.

The FY 1990 budget request of $1.6 billion submitted by President Bush represents a 24 percent increase over FY 1989 and is needed to elevate our battle against this disease. This request will enable PHS to implement the major objectives contained in the Report from the Second PHS AIDS Prevention and Control Meeting in Charlottesville, Virginia; the President's ten-point action plan against HIV which was based on the Report of the Presidential Commission on the HIV Epidemic; and certain portions of the Health Omnibus Programs Extension Act of 1988.

In 1988 alone, over 32,000 new cases of AIDS were reported. Through February 1989, over 88,000 AIDS cases have been reported to the Centers for Disease Control, including 1,440 cases in children less than 13 years of age. More than half of the reported cases have died. Each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and the Trust Territories have reported cases of AIDS. The PHS projects that between 1.0 to 1.5 million Americans may be infected already with HIV. In the absence of an effective treatment or therapy, it is predicted that all those infected with HIV will eventually die from this devastating disease.

Mr. Chairman, in response to this deadly threat, the priorities of the PHS are very clear. We will do everything humanly possible to expand our research and prevention activities to:

- o increase our knowledge and understanding about this disease process - its origin and nature, genetic and biologic properties of vital strains, the body's response to infection, possible differences in individual susceptibility to infection, risk factors, various modes of transmission, and the problems of prevalence and incidence;

- o develop vaccines to prevent HIV infection and develop drugs and therapies for those who are already infected; and,

- o inform and educate high-risk populations, the general public, health care workers, and school and college-aged populations to encourage individuals to minimize behavior that increases the risk of spreading or contracting HIV infection. Special emphasis is being placed on designing community-specific interventions which are tailored to the needs of individuals at risk as identified by their race, ethnicity, sex, drug use, sexual orientation, and socioeconomic status.

Mr. Chairman, extraordinary progress in the battle against HIV infection has been made in a relatively short period of time, more than against any other complex new disease in the history of medicine. I would like to share with you some of our more recent accomplishments.

PHS researchers are evaluating the use of a highly sensitive method for the detection of HIV. The polymerase chain reaction (PCR) technique has made it possible to identify HIV genetic sequences in infected individuals before they are positive by HIV antibody tests. This new technique is playing an important role in epidemiologic studies of HIV, for example, in the early detection of HIV infection in new born children, and should be useful in testing the efficacy of drugs and vaccines.

Using basic research techniques, scientists have now defined the entire genome of the HIV, and have delineated the functions of many of the viral genes. This information is helping to unravel the complicated process that determines how efficiently HIV replicates in cells. It also has implications for understanding latency, or the apparent inactivity of HIV in some infected cells. The National Institute of Allergies and Infectious Diseases has established National Cooperative Drug Discovery Groups, comprising teams of experts from biotechnology companies, pharmaceutical houses, universities, medical centers, and Federal agencies. A total of 28 groups are now funded. Using knowledge gained from many important scientific disciplines including virology, and molecular and structural biology, new agents are being designed to interfere with the viral lifecycle and combat the disease process. Several experimental drugs have emerged from their work, an unprecedented accomplishment. One of these, recombinant soluble CD4, is being tested in Phase I clinical trials.

Our extramural clinical trials effort, begun in 1986 with contracts awarded to 19 medical centers, has evolved with unprecedented speed into a nationwide network of 45 AIDS Clinical Trials Units including 13 Pediatric Units. This AIDS Clinical Trials Group has enrolled over 6,300 HIV-infected individuals in more than 60 different clinical studies. Twenty-five different agents have been studied, either alone or in combination.

Last year we reported the beginning of the first human trial of experimental AIDS vaccine. That study is continuing in our NIH intramural program, and this vaccine is also being tested in NIAID's six Vaccine Evaluation Units. More studies will have to be done to determine whether this vaccine will prove to elicit a protective immune response against HIV. Tests on a second candidate vaccine are underway and we expect that other candidate vaccines will be evaluated in Phase I trials in these units.

The National Institute of Child Health and Human Development supports a major multicenter clinical trial effort to study the effectiveness of intravenous gamma globulin to prevent multiple bacteria infections in children with AIDS. Other promising therapies are being studied in children at the pediatric AIDS clinical trial units and pediatric research centers across the country. We plan to expand these efforts.

In the prevention area the PHS has been initiating new information and education programs, as well as expanding existing ones to prevent the spread of this disease. HIV prevention programs exist in 50 states, five municipalities and six territories to provide counseling, testing and partner notification services and health education/risk reduction activities. The Centers for Disease Control (CDC) continue to direct a massive public information campaign with national, State, and local components. Between May 15 and June 15, 1988 CDC mailed a brochure entitled, "Understanding AIDS" to 107 million households. Approximately 345 community-based organizations received CDC support to implement activities aimed at preventing AIDS/HIV infection in racial and ethnic minorities. A $17 million (57 percent) increase is requested in FY 1990 for CDC programs targeted to high risk minority populations.

In the area of health care delivery, the Health Resources and Services Administration funded 21 (8 new) AIDS Service Demonstration Projects. In FY 1989, up to 25 new projects will be funded in communities with a lower prevalence of HIV.

Basic science, clinical, and demonstration research conducted by the Alcohol, Drug Abuse, and Mental Health Administration continue to increase our understanding of the neuroscientific, neuropsychiatric, behavioral, and psychosocial aspects of HIV and AIDS. Early data from Phase I clinical trials by intramural research scientists at the National Institute of Mental Health has shown that Peptide T, a potential blocker of the CD4 receptor in the brain has possible therapeutic efficacy with acceptable toxicity. Other studies have shown that synthetic peptide segments of the CD4 molecule inhibit infectivity by HIV and inhibit HIV-induced cell fusion.

One-third of AIDS cases reported in 1988 are linked in some way to intra-venous drug abuse (IVDA). Of these IVDA-associated AIDS cases, 89 percent have a history of IVDA; 8 percent were heterosexual partners of IVDA's; and 3 percent were children whose mother was an IVDA or was a sexual partner of an IVDA. The National Institute on Drug Abuse will expand its research and prevention activities from $120 million to $140 million in FY 1990 to address the IVDA problem.

The budget also proposes a $25 million contingency fund to respond instantly to any new opportunities that may arise during the year. We propose that the Secretary continue to exercise authority, upon approval of the Appropriations Committee, to redistribute AIDS resources among the PHS agencies.

In summary Mr. Chairman, the FY 1990 budget request of $1.6 billion is an increase of $311 million or 24 percent over the 1989 level of $1,289 billion. Increases are proposed in all aspects of the PHS-supported HIV research and prevention activities.

MEDICAL TREATMENT EFFECTIVENESS

The Fiscal Year 1990 budget request includes $52 million in obligational authority for a new appropriation entitled Medical Treatment Effectiveness. The purpose of this Departmental research initiative is to improve the effectiveness and appropriateness of health care provided to the public by enhancing our collective understanding as to which health care practices are most effective.

Many patient care procedures and interventions undertaken by physicians and other health care providers are of unproven medical necessity and effectiveness. Some tests and procedures, while appropriate under certain circumstances, when used in others may be inappropriate. Other tests and procedures may not be used often enough. Some tests and procedures may simply be ineffective under any circumstances. To address these problems, and in response to Bipartisan Congressional support for medical effectiveness research, the Department is requesting $52 million to greatly expand the Medical Treatment Effectiveness Initiative.

The first phase of this research initiative was developed by the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). In FY 1988, pursuant to the "Omnibus Budget Reconciliation Act of 1986," NCHSR established a Patient Outcome Assessment Research Program. This program, which builds on NCHSR's 15 year history of support for research on the impact of medical practices on patient outcomes, was reauthorized last fall in the "Technical and Miscellaneous Revenue Act of 1988." In FY 1990, our efforts to improve the scientific basis of medical decision-making will include conducting research at NCHSR; and, in collaboration with the Health Care Financing Administration and the Health Resources and Services Administration, collecting, developing and analyzing data, and finally, disseminating the findings to clinical practitioners.

In response to increasing concern in the Executive and Legislative branches of Government over the quality and effectiveness of American medical care, we are requesting $52 million, a significant increase of $46 million over the FY 1989 level. In support of this increase, it is important to recognize that medical effectiveness research has significance for saving lives, improving the quality of medical care, increasing and maintaining functional abilities of patients, conserving resources and reducing malpractice suits.

PUBLIC HEALTH SERVICE MANAGEMENT

The Fiscal Year 1990 budget request of $190 million for the PHS Management appropriation is a net reduction of $3.8 million below the FY 1989 comparable level of funding. This reduction primarily reflects a change in the planned source of funds for the National Medical Expenditure Survey in the National Center for Health Services Research and Health Care Technology Assessment.

The 1990 budget request includes $13.8 million of budget authority for the National Center for Health Services Research and Health Care Technology Assessment (NCHSR). The Center is the central focus of Federal efforts in health services research on problems related to

the quality, cost, organization, and delivery of health services. The 1990 request is a decrease of $4.9 million in budget authority below the FY 1989 level. However, we are requesting additional obligational authority, for the National Medical Expenditure Survey and the Hospital Studies Program, from funding authorized under Section 2513 of the PHS Act. These funds will maintain NCHSR at approximately the same level of operations as in FY 1989.

The budget request presented to you today includes $9.5 million for the Adolescent Family Life program to continue its demonstration and research program at the 1989 funding level. This is a $3.5 million increase over the January 9, 1989 request which proposed phaseout of the program. The issue has been re-examined, and as a result, President Bush's budget has restored the funding level and rescinded the phaseout plans. The Administration is particularly supportive of the program's unique focus on promoting adoption as a positive alternative to teens facing a crisis pregnancy.

In FY 1990, $138.4 million is being requested for grants and program administration costs for the State Administered Family Planning program. Funding for the Family Planning categorical program has previously been appropriated to the Health Resources and Services Administration although the program is administered by the Office of the Assistant Secretary for Health, Office of Population Affairs.

The proposed State administered program will support direct awards to the States and territories and will provide the States both the resources and control over the resources to deliver voluntary family planning services that are responsive to and in accordance with State law and other State administered health care programs.

The budget request of $4.5 million for the Disease Prevention and Health Promotion activity and the budget request of $1.5 million for the Physical Fitness and Sports activity provide support for on-going program activities. The budget includes a request of $3 million for the Office of Minority Health to continue its role as the focal point for the formulation and development of strategies to reduce the disparity in the health status between minority and non-minority populations and to focus on modifying those behavior patterns or preventable conditions which contribute to excess mortality among minorities. In FY 1990, the Office of Minority Health will continue the risk reduction coalition grant program and manage a Department-wide coordination and planning process to develop goals and objectives in minority health.

For the management and direction of the Public Health Service (PHS), we are requesting $19.6 million. This request will support the current level of activity and staffing needed to assist the Assistant Secretary for Health in carrying out his responsiblity as line manager of the PHS.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

The Retirement Pay and Medical Benefits for Commissioned Officers appropriation provides retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

The FY 1990 budget request for this entitlement program is $110.2 million, an increase of $5.9 million over the 1989 level and includes a reserve fund of $5 million and $3.1 million for military service credits. The reserve fund will be available only to the extent necessary for unanticipated costs in the budget estimates. The amount for military service credits is requested to reimburse the Social Security Administration to cover the value of non-wage income such as food, shelter, and medical care.

Mr. Chairman, I will be pleased to answer any questions you may have.

BIOGRAPHY OF DR. JAMES F. DICKSON, III

James F. Dickson III, M.D., has been the Senior Advisor for Environmental Affairs, Office of the Assistant Secretary for Health for the past several years, and was recently named Acting Assistant Secretary for Health.

As Acting Assistant Secretary for Health, Dr. Dickson directs the activities of the Public Health Service, which includes the Food and Drug Administration; the Health Resources and Services Administration; the Indian Health Service; the Centers for Disease Control; Agency for Toxic Substances and Disease Registry; the National Institutes of Health; and, the Alcohol, Drug Abuse and Mental Health Administration.

Dr. Dickson was born in Boston, Massachusetts, on May 4, 1924. He graduated from Boston Latin School in 1941; Dartmouth College in 1944; and received his medical degree from Harvard Medical School in 1947.

He was trained as a general and thoracic surgeon on the Harvard Surgical Service at the Boston City Hospital. During the Korean War, he was Chief of Surgery at the 8055 Mobile Army Surgical Hospital in Korea.

From 1954 to 1960 he was engaged in the practice of thoracic and cardiovascular surgery and in cardiovascular research in Boston and New York City.

From 1961 to 1965 he was a Special Fellow of the National Institutes of Health at the Electronic Systems Laboratory at Massachusetts Institute of Technology. There he engaged in the application of communication and control theory for the study of biological systems and in the development of computer-oriented engineering systems for biomedical research and health care. During this period he was active on national committees concerned with science, technology and health and served as Senior Consultant for Health with the President's Commission on Technology, Automation and Economic Progress.

From 1965 to 1981 Dr. Dickson was:

- Director of Engineering in Biology and Medicine at the National Institutes of Health
- Director of Health for the President's Advisory Council on Management Improvement

- Deputy Assistant Secretary for Health
- Acting Assistant Secretary for Health

Dr. Dickson is an Assistant Surgeon General, a member of the Institute of Medicine of the National Academy of Sciences, a Diplomate of the American Board of Surgery, a Fellow of the American College of Surgeons and a Fellow of the Institute of Electrical and Electronics Engineers.

Dr. Dickson is the author of fifty professional papers on surgery and biomedical research and the editor of six books dealing with science, technology and medicine. His biography appears in The Directory of Medical Specialists as well as American Men and Women of Science.

INTRODUCTION OF ASSOCIATES

Dr. DICKSON. Yes, sir.

Thank you, Mr. Chairman. May I introduce those accompanying me here at the table?

Senator HARKIN. Please do so.

Dr. DICKSON. From my far left, Dr. Gary Noble, the Deputy Director for AIDS at the Centers for Disease Control; next, Dr. Anthony Fauci, the Director of the National Institute for Allergy and Infectious Diseases at the National Institutes of Health; on my immediate left, Mr. Harell Little, the Director of the Division of Public Health Service Budget; from my far right, Mr. Dennis Williams, the Department's Deputy Assistant Secretary for Budget; next, Dr. Frederick Goodwin, the Director of the Alcohol, Drug Abuse, and Mental Health Administration; and on my immediate right, Dr. James Allen, the Acting Director of our National AIDS Program Office.

I am also accompanied by other members of the Office of the Assistant Secretary for Health and other segments of the Public Health Service who relate variously to the programs that will be under discussion this morning.

OPENING STATEMENT

Mr. Chairman, I appreciate the opportunity to appear here today to discuss the fiscal year 1990 budget request for the appropriations in the Office of the Assistant Secretary for Health. That includes the National Human Immunodeficiency Virus Program request of $1.6 billion, the Medical Treatment Effectiveness request of $52 million, the Public Health Service Management request of $190 million, and the Retirement Pay and Medical Benefits for Commissioned Officers request of $110 million. Except for the National Human Immunodeficiency Virus Program and the Adolescent Family Life Program, the fiscal year 1990 OASH budgets are included in the Bush budget residual freeze category. In general, the funding levels addressed here today were proposed in the fiscal year 1990 Reagan budget.

As for the national human immunodeficiency virus epidemic, as you well know, Mr. Chairman, AIDS is our No. 1 public health priority. The fiscal year 1990 budget request of $1.6 billion submitted by President Bush represents a 24 percent increase over fiscal year

1989 and is needed to elevate our battle against this disease. This request will enable the Public Health Service to implement the major objectives contained in the report from the second Public Health Service AIDS prevention and control meeting in Charlottesville, VA; the President's 10-point action plan against HIV which was based on the report of the Presidential Commission on the HIV Epidemic; and certain portions of the Health Omnibus Programs Extension Act of 1988.

The budget also proposes a $25 million contingency fund to respond instantly to any new opportunities that may arise during the year.

We propose that the Secretary continue to exercise authority, upon approval of the Appropriations Committee, to redistribute AIDS resources among the Public Health Service agencies.

In 1988 alone, over 32,000 new cases of AIDS were reported. Through February 1989, over 88,000 AIDS cases have been reported to the Centers for Disease Control, including 1,440 cases in children less than 13 years of age. More than one-half of the reported cases have died. The Public Health Service projects that between 1 million and 1.5 million Americans may be infected already with HIV. In the absence of an effective treatment or therapy, it is predicted that all those infected with HIV will eventually die from this devastating disease.

Mr. Chairman, in response to this deadly threat, the priorities of the Public Health Service are very clear. We will do everything humanly possible to expand our research and prevention activities in order to: First, increase our knowledge and understanding about this disease process; second, develop vaccines to prevent HIV infection and develop drugs and therapies for those who are already infected; and third, inform and educate individuals to minimize behavior that increases the risk of spreading or contracting HIV infection.

Mr. Chairman, extraordinary progress in the battle against HIV infection has been made in a relatively short period of time, more than against any other complex new disease in the history of medicine. I have outlined for you some of our more recent accomplishments in the full statement submitted for the record.

For the area of medical treatment effectiveness, the fiscal year 1990 budget request includes $52 million in obligational authority for a new appropriation entitled "Medical Treatment Effectiveness." The purpose of this departmental research initiative is to improve the effectiveness and the appropriateness of health care provided to the public by enhancing our collective understanding as to which health care practices are most effective.

Many patient care procedures and interventions undertaken by physicians and other health care providers are of unproven medical necessity and effectiveness. Some tests and procedures, while appropriate under certain circumstances, when used in others, may be inappropriate. Other tests and procedures may not be used often enough. Some tests and procedures may simply be ineffective under any circumstances. To address these problems, and in response to bipartisan congressional support for medical effectiveness research, the Department is requesting $52 million to greatly expand the medical treatment effectiveness initiative.

For the area of public health service management, the fiscal year 1990 budget request of $190 million for the public health service management appropriation is a net reduction of $3.8 million below the fiscal year 1989 comparable level of funding. This reduction primarily reflects a change in the planned source of funds for the national medical expenditure survey in the National Center for Health Services Research and Health Care Technology Assessment.

The 1990 budget request includes $13.8 million of budget authority for the National Center for Health Services Research and Health Care Technology Assessment. The 1990 request is a decrease of $4.9 million in budget authority below the fiscal year 1989 level. However, we are requesting additional obligational authority, for the National Medical Expenditure Survey and the Hospital Studies Program, from funding authorized under section 2513 of the Public Health Service Act. These funds will maintain the center at approximately the same level of operations as in fiscal year 1989.

The budget request presented to you today includes $9.5 million for the Adolescent Family Life Program to continue its demonstration and research program at the fiscal year 1989 funding level. This is a $3.5 million increase over the January 9, 1989 request, which proposed phase-out of the program. The issue has been reexamined, and as a result, President Bush's budget has restored the funding level and rescinded the phase-out plan. The administration is particularly supportive of the program's unique focus on promoting adoption as a positive alternative to teens facing a crisis pregnancy.

In fiscal year 1990, $138.4 million is being requested for grants and program administration costs for the State Administered Family Planning Program. The proposed State administered program will support direct awards to the States and territories and will provide the States both the resources and control over the resources to deliver voluntary planning services that are responsive to and in accordance with State law and other State administered health care programs.

The budget request of $4.5 million for the disease prevention and health promotion activity and the budget request of $1.5 million for the physical fitness and sports activity provide support for on-going program activities.

The budget includes a request of $3 million for the Office of Minority Health to continue its role as a focal point for the formulation and development of strategies to reduce the disparity in the health status between minority and nonminority populations and to focus on modifying those behavior patterns or preventable conditions which contribute to excess mortality among minorities.

For the management and direction of the Public Health Service, we are requesting $19.6 million. This request will support the current level of activity and staffing needed to assist the Assistant Secretary for Health in carrying out his responsibility as line manager of the Public Health Service.

For the area of retirement pay and medical benefits for commissioned officers, the fiscal year 1990 budget request for this entitlement program is $110.2 million, an increase of $5.9 million over the

fiscal year 1989 level, and includes a reserve fund of $5 million, and $3.1 million for military service credits.

HISTORY OF THE AIDS EPIDEMIC

Dr. DICKSON. Mr. Chairman, before going to any questions you may have, with your permission, I would like to ask Dr. Allen to make a brief chart presentation on AIDS, our No. 1 health priority.

Senator HARKIN. Thank you.

Dr. ALLEN. Thank you, Mr. Chairman.

The first cases of AIDS were reported to the Centers for Disease Control in 1981. Since that time, the numbers of cases have continued to increase dramatically.

The first appropriations for AIDS were made in 1982 with a budget of $5.6 million. As you can see, appropriations have increased dramatically since that time, and for fiscal year 1990 we are requesting an appropriation of $1.6 billion. This is a growth in funding that is unparalleled in the Public Health Service's history.

I would like to give you a few of the epidemiological facts that underlie this dramatic increase in funding.

First, we estimate that the number of infected persons in the United States ranges from 1 million to 1.5 million. These people are infected with HIV, the virus that causes AIDS. Many of these people—in fact, most today—are asymptomatic. They will in the future, however, become ill and be diagnosed with AIDS and ultimately die from that infection.

NUMBER OF AIDS CASES REPORTED

Cumulatively through March 20, 1989, we have had almost 90,000 cases reported, of which more than 51,000 were known deaths, which is approximately 57 percent of the total cases.

Senator HARKIN. Cumulative cases reported, 89,671. That is not HIV positive.

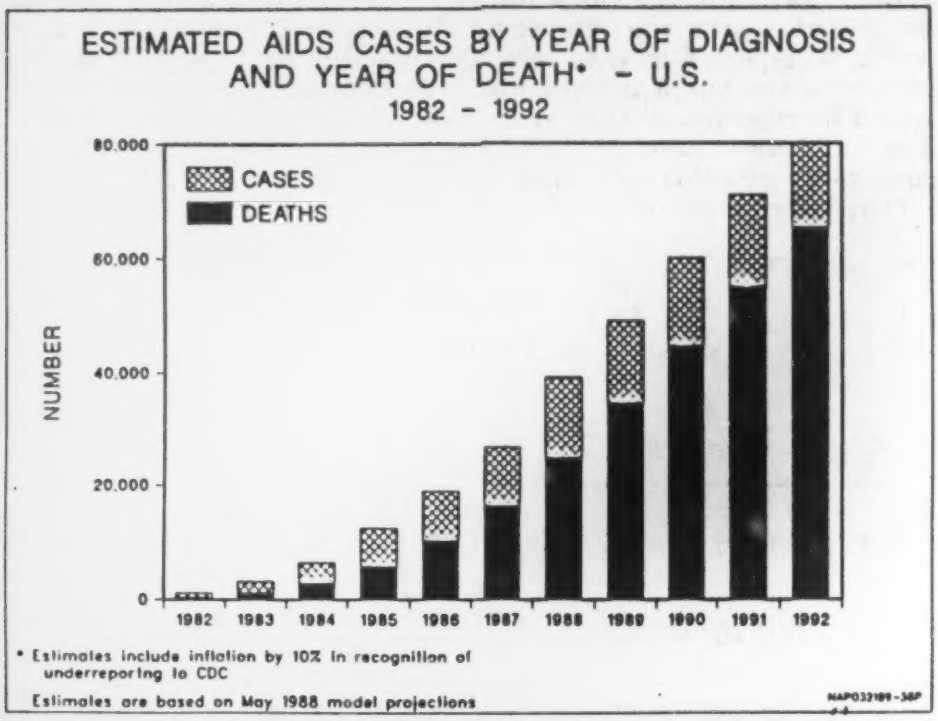
Dr. ALLEN. These are cases of AIDS, people who have clinical illness called AIDS.

Senator HARKIN. That is cumulative going back to 1981.

Dr. ALLEN. Yes; that is going back to the first cases recognized in 1981.

In calendar year 1988, we have had almost 33,000 cases reported with almost 14,000 deaths. That is a 52-percent increase in cases over the 21,600 reported in 1987.

[The information follows:]



This graph is an estimate of the numbers of cases diagnosed by years since the beginning of the epidemic. As you can see, there is no leveling off or end of the epidemic in sight yet. In 1992, we project on a statistical basis that we will have approximately 80,000 cases diagnosed in the United States. Most of the cases that occur between the current time and 1992 will occur in people who are already infected with HIV.

PERIOD OF INCUBATION

Senator HARKIN. Now, what is the average time, the median time?

Dr. ALLEN. The median time we believe from infection of the virus and diagnosis of AIDS is 8 to 10 years. By median, we mean that at 8 to 10 years, about one-half of the people who are infected at time zero will have been diagnosed with AIDS.

Senator HARKIN. What is the longest time on record that you know of?

Dr. ALLEN. Since we don't know for sure when the earliest people were infected, we don't know for certain. There have been documented cases of people being infected at 9 and 10 years and still be asymptomatic, but that is very uncommon. By the time you reach 9 or 10 years, 85 to 90 percent of the people are clinically ill although they may not have been diagnosed with AIDS. But they do have clinical illness that is attributable to HIV infection.

Senator HARKIN. Let me see that last chart again. Something caught my eye on that. The number of deaths keep going up quite rapidly, but the number of cases seem to remain the same.

Dr. ALLEN. No; the cases would be the entire graph. From the bottom up to the top represents the total number of cases that would be reported in that year, diagnosed in that year. From the bottom to the top of the red would be the numbers of deaths that would be reported in that year. So, they are really superimposed. The numbers of cases is 80,000 new cases. I think we can explain some of that on this next chart.

[The information follows:]

PUBLIC HEALTH SERVICE
AIDS - Future Problem *

1992 - Projected	
Cumulative Cases Diagnosed	365,000
Cumulative Deaths	263,000
AIDS Patients Requiring Treatment in 1992	172,000
Estimated Medical Care Cost	$5-$13 Billion

* Charlottesville Estimates, June 1988

Senator HARKIN. I guess the number of infected remains about the same. Is that about right?

Dr. ALLEN. The numbers of infected are going up to some degree, but it is difficult to estimate that. Much of our budget for surveillance and epidemiologic studies is going to try to determine the number of newly infected cases that are still occurring.

Cumulatively we estimate by 1992 that we will have 365,000 cases since the beginning of the epidemic. That would be an 11-year period. Cumulative deaths at that point will be about 263,000.

We estimate that in calendar year 1992 there will be 172,000 patients who will require medical care during at least some or all of that year. I think it is important to point out that that number is almost double the cumulative number of cases reported through 1988. We estimate that the medical care cost in that year at 1992 will be in the range of $5 million to $13 million.

Senator HARKIN. That is just for 1992.

Dr. ALLEN. That is just for 1992.

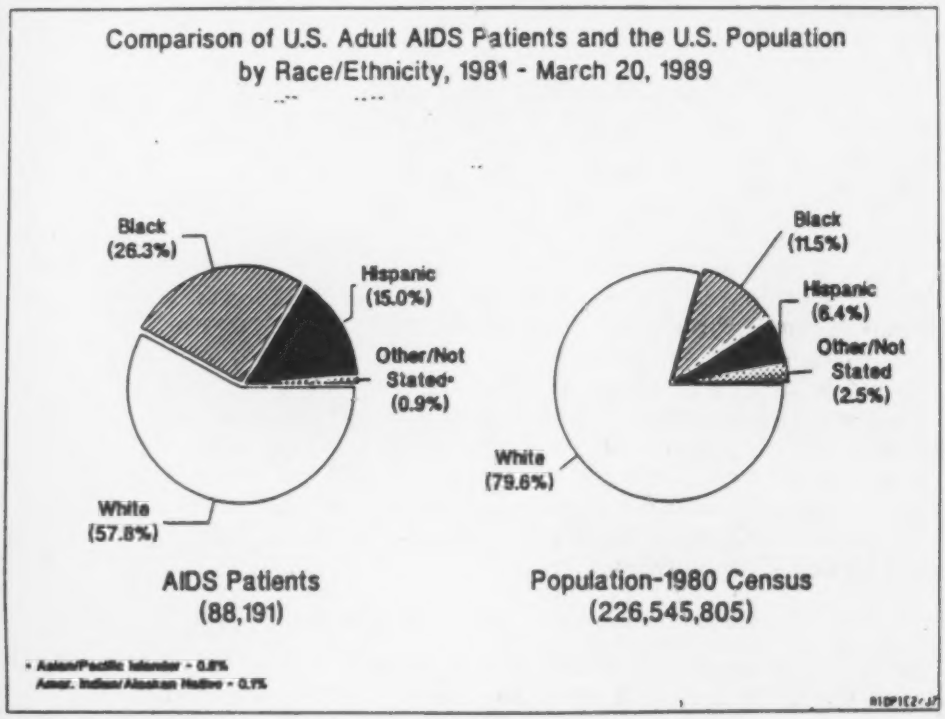
Senator HARKIN. And when you say medical care costs, that is for treating those who have been diagnosed as having AIDS from the point they are diagnosed to their death.

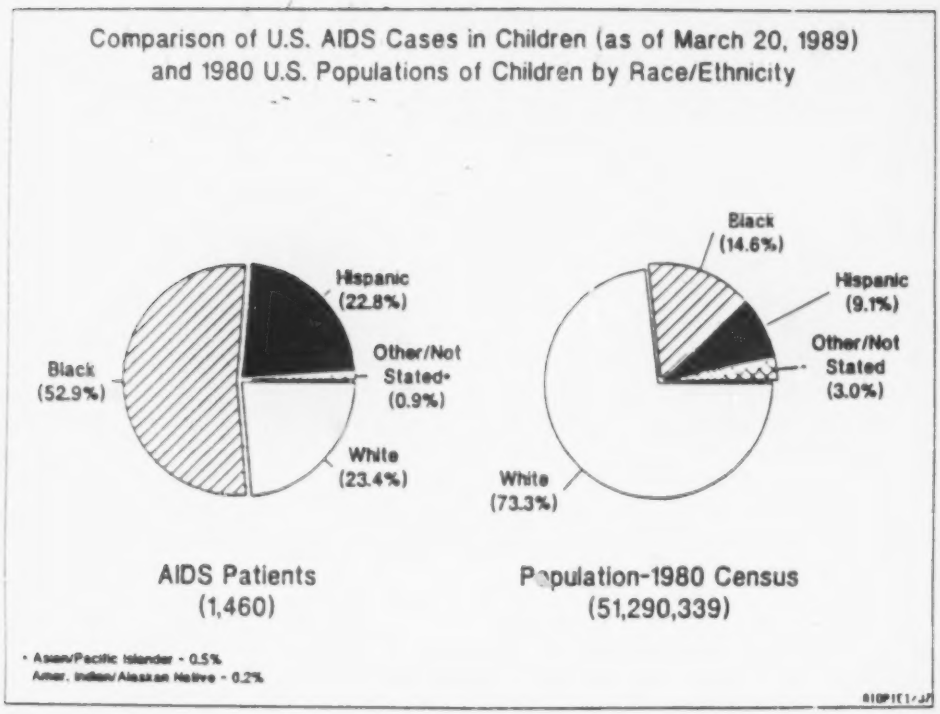
Dr. ALLEN. That's correct, in that 1 year. If a person lives for 2 or 3 years, that does not count. That is just the estimated cost in that year.

AIDS AMONG DRUG USERS AND MINORITY POPULATIONS

An important variable risk factor for AIDS and HIV infection in the United States is intravenous drug use. In calendar year 1988, one-third of all the AIDS cases were associated in some way with intravenous drug use whether they were directly drug users themselves, sexual partners of drug users, or children born to drug users or their sexual partners.

This risk factor has had a disproportionate impact on our minority population, whereas among the whites with AIDS only 16 percent are associated with drug use. Among our black population, it is almost 53 percent. In our Hispanic population, it is 55.5 percent of cases are associated with intravenous drug use. In addition, of the children born with AIDS, 70.2 percent are born to mothers who are intravenous drug users or mothers who are sex partners of





I would like to in the next two graphs reemphasize the impact that AIDS has had on our minority populations. The chart on the right shows the population distribution from the 1980 census. The chart on the right shows the AIDS cases in adults.

Approximately 80 percent of our population is white, but only 58 percent of the AIDS cases are white; 11 percent of our population is black, but 26 percent of the cases are black; 6 percent of our population is Hispanic. Fully 15 percent of our cases have been in our Hispanic population.

In children, it is even more dramatic; 73 percent of the population of children are white. Only 23 percent of the cases are white. These are children less than 13 years of age. Of the children, 14.5 percent of the population is black. Almost 53 percent of the cases are black. In our Hispanic population, children represent about 9 percent, compared with almost 23 percent of the cases. The AIDS risk for a black child is approximately 11 times that for a white child in the United States.

FISCAL YEAR 1990 BUDGETED AIDS ACTIVITIES

In the next graph, I would like to show you briefly how we plan to use the Public Health Service budget that we are requesting for fiscal year 1990. We have three primary areas: Research, prevention, and services.

For research, we are requesting $1.046 billion which is approximately 65 percent of the total; for prevention, we are requesting $438 million, approximately 27 percent; for services, $91 million; and for a new category, a contingency fund as recommended by the

presidential commission, we are requesting $25 million to give us the flexibility to target new areas that we learn about or new areas of research that become apparent in the next year.

Public Health Service HIV/AIDS Research (dollars in millions)

	1988	1989	1990	Change 89/90	
Disease Studies and Surveillance	$375	$490	$604	+$114	(+23%)
Epidemiology and Surveillance (non-add)	(135)	(171)	(219)	(+ 48)	(+28%)
Therapeutics	200	263	335	+72	(+27%)
Vaccines	54	88	107	+19	(+22%)
Total, RESEARCH	$629	$841	$1,046	+$205	(+24%)

Public Health Service HIV/AIDS Prevention (dollars in millions)

	1988	1989	1990	Change 89/90	
Information and Education					
General Public	$63	$42	$50	+$8	(19%)
School and College Aged	29	35	42	+ 7	(+20%)
High Risk or Infected Persons	177	245	299	+54	(+22%)
Testing, counseling, referral (non-add)	(67)	(101)	(120)	(+19)	(+19%)
Health Care Workers	28	34	38	+4	(+12%)
Subtotal, Information and Education	297	356	429	+73	(+21%)
Prevention of Transfusion-related AIDS	9	4	9	+5	+25%)
Total, PREVENTION	$306	$360	$438	+$78	(+22%)

Public Health Service
HIV/AIDS
(dollars in millions)

	1988	1989	1990	Change 89/90	
Research	$629	$841	$1,046	+$205	(+24%)
Prevention	306	360	438	+78	(+22%)
Services	27	88	91	+3	(+3%)
Contingency Fund	—	—	25	+25	(+100%)
Total,PHS	$962	$1,289	$1,600	+$311	(+24%)

I would like to just show you one final chart which is the allocation by agencies. All of the agencies of the Public Health Service are involved in our fight against AIDS. Although this committee does not normally consider appropriations for the Food and Drug Administration and the Indian Health Service, it is important to recognize that all of the agencies are involved in this battle. Ninety percent of our AIDS budget is requested for the areas of research and prevention and would go to the National Institutes for Health, the Centers for Disease Control, and the Alcohol, Drug Abuse, and Mental Health Administration.

Thank you.

Public Health Service
HIV/AIDS
(dollars in millions)

	1988	1989	1990	Change 89/90	
FDA	$30	$63	$57	-$ 6	(-10%)
HRSA	37	55	56	+ 1	(+2%)
IHS	—	1	1	—	—
CDC	305	379	474	+95	(+25%)
NIH	473	604	753	+149	(+25%)
ADAMHA	112	174	218	+44	(+25%)
OASH	4	13	16	+ 3	+23%)
Contingency	—	—	25	+25	(+100%)
Total-HIV/AIDS	$961	$1,289	$1,600	+$311	(+24%)

Dr. DICKSON. Mr. Chairman, we will be pleased to answer any questions you may have.

THE SPREAD OF AIDS

Senator HARKIN. Thank you very much, Dr. Allen and Dr. Dickson.

As I detected and as my staff has told me, the new infection rate among gay men has come down sharply and is now less than 1 percent. The HIV infection rate among military recruits and blood bank donors has come down slightly in the last year. The HIV infection rate among Job Corps applicants and those admitted to the group of hospitals CDC is tracking has been flat over the last year.

You estimate that between 1 million and 1.5 million Americans are infected with the virus.

What do you consider to be—I guess this question would be for Dr. Noble of CDC—the likelihood of AIDS spreading more widely into the general population?

Dr. NOBLE. The biggest increase of new infections is among the IV drug abuse community and in the sexual and needle sharing partners of the IV drug users and in the children born to HIV infected women.

As you indicate, the rate of new infections in homosexual men is down particularly in the white homosexual population. We are not convinced that the figures are quite as good as some indicate. For example, in San Francisco, you mentioned the rate of new infections may be in the vicinity of 1 percent per year, but there are other areas of the country where we haven't done as well with the homosexual population either.

The rate of new infections in IV drug users in New York City and New Jersey, for example, continues to go up. That is the area of greatest concern to us.

You asked whether it would spread into the general population. It depends on how you define——

THE ROLE OF DRUG ABUSE IN THE SPREAD OF AIDS

Senator HARKIN. It seems to be confined to IV drug users. If any increase in infection is taking place, that is where it is taking place.

Dr. NOBLE. That is clearly the population at greatest risk. The percentage of heterosexuals infected is highest through the IV drug abuse connection, about 55 percent of the heterosexually transmitted AIDS cases reported are related to IV drug abuse.

Senator HARKIN. I understand that in New York City, one out of every 61 babies born is HIV positive. In inner city hospitals in Baltimore and Newark, the infection rate among emergency room admissions is 5.3 percent.

Does this high infection rate in these inner city populations suggest that HIV infection may well spread across the Nation, or are these populations fairly contained?

Dr. NOBLE. This is a reflection of the problem we just discussed, that is, IV drug abuse and the sexual partners of IV drug abusers by and large.

Now, it is not just IV drug use. We should also recognize the importance of crack abuse. For example, we have found that there has been a tremendous increase in the rate of new syphilis cases between 1986 and 1987, and continuing into 1988, and that this increase has been greatest for black and Hispanic men and women. There has been no increase in syphilis cases for white women, and there has actually been a decrease in white males, largely reflecting the decrease in the male homosexual activities that lead to sexually transmitted diseases, including syphilis.

So, the figures you cite for newborn babies in these larger inner cities is a reflection of the IV drug abuse and the crack abuse since sex is often traded for crack.

AIDS INFORMATION MAILER

Senator HARKIN. Last year Congress funded a mailer that went to every household, 107 million households. We are also spending $261.9 million this year for various prevention and education efforts.

Dr. Dickson, can you tell us anything about the effectiveness of these efforts? Do you feel that Americans are better educated about the risks of AIDS and how they can avoid it?

Dr. DICKSON. I can tell you what we understand at this point, Mr. Chairman. In a statistical sense, of the 60 odd percent of the people who remembered receiving this mailing, 79 percent of those who received it said that they had actually read it. We believe it was effective in decreasing some misconceptions about AIDS and its infectiousness, such as the misconceptions that the disease can be transmitted by mosquitoes or by a child in school whose blood is infected with the virus.

I think overall, and in a most general sense, understanding something is one thing, but translating it into behavioral change is another.

EDUCATION EFFORTS THROUGH TELEVISION MESSAGES

Senator HARKIN. Let's face it, most Americans don't read the newspapers or read mailers, they watch television. What are we doing in terms of promoting public service announcements by the networks? Are the networks doing anything on this during prime time?

Dr. DICKSON. Yes; they are participating in that.

Senator HARKIN. Have they been making any prime time announcements?

OUTREACH PROGRAMS FOR AIDS

Dr. DICKSON. Some of them are. We have a program at the Centers for Disease Control that has been developed over the past 2 or 3 years to this end. I would like Dr. Noble to make a comment with respect to that.

Dr. NOBLE. The effort to reach the general public has been through public service announcements on television, in print ads, and in radio commercials. To date, over $26 million of free time has been donated since the campaign was launched in October

1987. It is not as much prime time as we would like, but there have been a number of good prime time commercials.

There is a new phase that is to be launched in the next month or so for parents and youth. That is a very important part of the population to reach.

As you say, many people don't read. We are extending this effort to the hard-to-reach through youth groups, and we are working to evaluate street outreach. Street outreach is a very costly process because it is very much a one-on-one kind of effort.

The question has been raised whether we should pay for television advertising. The National Academy of Sciences' National Research Council report has recommended paid advertising purchased by the Federal Government. We are interested in evaluating that, but we are concerned that it would drive out the donated time not only for HIV public service announcements, but for all of the other health announcements that are donated.

AIDS TREATMENT ACTIVITIES

Senator HARKIN. Let's talk a little bit about treatment. Between now and 1992, I understand that you project 270,000 new cases of AIDS will be diagnosed.

With 1 million to 1.5 million people infected with the virus and a median of 7 or 8 years?

Dr. ALLEN. A median of 8 to 10 years.

Senator HARKIN. From that chart of yours, it looks like we are going to have an explosion here by about 1992 compared to what we have right now, at least double it looks like. It is a 52 percent increase I think you said.

Last year the Congress authorized, and the President signed into law, a $100 million formula grant program for home and community-based care. Why didn't the administration request funding for this new program?

Dr. DICKSON. Mr. Chairman, first I should say that, in the most general sense, we believe that patients with AIDS and patients whose blood is infected with the virus should receive care in the same way that other patients in our population who have serious illnesses receive treatment. We also are concerned that solutions for care may arise that actually foster separate solutions that are not integrated within our established health care systems. In essence, we believe we do have to rely, including in the AIDS situation, on our mixed private-public system for financing support.

We have had activities, as you know, broadly provided by the Federal Government through Medicaid and Medicare, and we are involved in demonstration projects.

However, to the point of your question, during the processes of evaluating our final budget presentations to the Office of Management and Budget, and within the Department, we had proposed that $50 million be applied in the area you were speaking to. As it was evaluated at the departmental level, it was felt that on the matter of budget priorities, this money would not be proposed for us. In a budget priority sense, the feeling was that the funds available for research and prevention at this time were more important. So, it was a budget priority issue within the Department.

As I said, we in the Federal Government are providing considerable support, some $700 million in 1990, both through Medicare and Medicaid payments. Also, through our Health Resources and Services Administration we will be providing in 1990 some $26 million for service demonstrations, some $11 million for AIDS services, both in our community health centers and in our migrant health centers. In the National Institute for Drug Abuse, for 1990, we are proposing some $40 million that will be used for drug abuse treatment demonstrations.

Senator HARKIN. You recommended $50 million and OMB said no.

Dr. DICKSON. No, sir; within the Department. That was not sent on to OMB. The Department set its priorities, and this request was not included.

AZT TREATMENT

Senator HARKIN. Let me ask you a question about AZT.

Dr. Fauci, I understand the NIH has had a clinical trial under way for 1 year testing whether or not HIV infected individuals should start using AZT before they actually contract AIDS. I understand many HIV positive people already do use AZT and are not waiting for the results of your trial.

When do you believe NIH will be prepared to announce the findings of this trial?

Dr. FAUCI. The trial in question, Mr. Chairman, is a trial of approximately 2,500 to 3,000 seropositive, healthy individuals that are divided into placebo or AZT groups. It is asking the question of whether or not giving AZT chronically will prevent the onset of symptoms.

The way the study is set up is that about every 3 months or so we have an impartial data and safety monitoring board look at the data and determine if it has yet reached statistical significance. It is really impossible for me to give you a time or date, when we will know the results. We will be looking for a certain percentage of people who don't receive the drug to become ill, compared to a lesser percentage who do receive the drug.

I suspect from what we know about AZT and its effect on the virus in individuals who already have symptoms, that this information will be forthcoming, at least within the next year and probably sooner.

Senator HARKIN. With an annual cost of $8,000 to $10,000 a year for AZT—is that what it costs to take AZT?

Dr. FAUCI. That's what it costs people who take AZT for a year, approximately $8,000 to $10,000.

Senator HARKIN. With over a million people for whom it may be recommended, and with the Federal Government now paying for AZT for roughly one-third of those receiving it, obviously this could get to be very expensive.

If the clinical trial findings are positive, do you expect AZT would be recommended for all HIV positive people or for some subset of this group?

Dr. FAUCI. Well, that depends on how the data falls out. Certainly, if the study is positive, it will be recommended for a subset. It is

likely that the subset will be stratified depending upon the level of their T4 lymphocytes which is a marker of the effect of the virus on the immune system. If the study shows that it prevents the onset of symptoms in seropositive individuals regardless of their immunological status, then you could be talking about 750,000 to a million people for which it would be recommended. If it is a subset, for example, of individuals with T4 counts of 400 or less, or 300 or less, or 200 or less, then that number becomes less and less.

SOURCE OF FUNDS FOR AZT TREATMENT

Senator HARKIN. Dr. Dickson, you spoke of a funding mechanism. What kind of funding mechanism are we looking at if we are going to be buying AZT for everybody?

Dr. DICKSON. Mr. Chairman, as you know, in the recent past we did reprogram $5 million to funding for AZT to carry us through the end of this fiscal year. That was in addition to the $10 million that previously had been reallocated from our other AIDS moneys. This, as we have been discussing, is expensive at $8,000 a year per patient, and in this area it is likely to get much worse in terms of expense as additional therapies become available.

Basically, and what is most important to us, is that the Public Health Service is by and large a risk assessment rather than a risk management organization. It is very damaging to us to have to take research and prevention money and reallocate it into areas for the delivery of services when, as I say, our business is primarily risk assessment, rather than risk management.

We do hope that over the next 6 months we will be engaging in discussions with the Congress in the interest of finding some other alternate mechanisms for getting after this problem. We expect, in the interim, that the $5 million that has been reprogrammed will bridge the gap until the States may be able to take over a larger part of the burden. I believe, Mr. Chairman, that Secretary Sullivan wrote to you on his hope that this would serve as a bridge to a further point where, through negotiations with the Congress, we might be able to come to some other conclusions about a mechanism for funding this.

It is very, very damaging to us to lose money from our research and prevention efforts. We don't feel that providing treatment is our primary mission.

Senator HARKIN. Well, I guess I am just looking ahead. Let me ask you this, Dr. Fauci. AZT obviously is not a cure. It just postpones the onset of the symptoms.

Dr. FAUCI. Yes.

Senator HARKIN. For how long?

Dr. FAUCI. We don't know right now because we haven't had patients on AZT long enough. The studies started just a couple of years ago. The ultimate hope is that either AZT or a less toxic drug with the same type of effect as AZT, or a combination of AZT with another drug or two other drugs can be administered chronically over a long period of time so that people can have several years, if not decades, of meaningful life while they are harboring the infection. The infection may be kept under check so that it doesn't multiply at the rapid rate which it does in an untreated person.

THE COST OF AZT TREATMENT

Senator HARKIN. If you took a million people, and if you said $10,000 per year per person, you are talking about $10 billion per year. Do you expect the development of any new drugs that might help drive this price down?

Dr. FAUCI. I think, as in any situation in the marketplace, that if another drug is developed which clearly shows in a scientific study to have the same or even a better effect than AZT, I would be absolutely certain that the price of that drug will be less and the price of AZT will come down. Currently there are a number of drugs in clinical trials.

Senator HARKIN. You just raised a good point. You said if new drugs come on, it lowers the price of AZT.

Dr. FAUCI. Right.

Senator HARKIN. Well, is AZT being fairly priced right now?

Dr. FAUCI. It is impossible for me to say as a scientist doing a clinical trial because the formulas that the drug companies give are somewhat inscrutable. As you well know—if you ask them how much it costs to make AZT, they consider that an inappropriate question because the pricing of AZT takes into account the many drugs they had to test that failed before they got to AZT.

Senator HARKIN. I see.

Dr. FAUCI. So, if you are going to ask me is AZT as such overpriced, that is an impossible question for me to answer. I think if AZT was in a vacuum and that was the only drug they ever tested and they put no money into anything else, then certainly it would be overpriced.

Senator HARKIN. I understand.

RESEARCH INTO THE EPIDEMIOLOGY OF AIDS

Over the last year, Dr. Fauci, a lot has been reported in the popular press regarding ways to interfere with the viral life cycle based on new understandings of the structure of the virus and how it couples with and invades the healthy T-cells and other cells.

Could you describe very briefly for us the progress being made in research to frustrate the HIV virus' capability to invade and couple with healthy cells?

Dr. FAUCI. It comes under the broad category of targeted drug development, and there are two components to that.

The first is to delineate as best as possible the function and the products of the genes of HIV so that you can essentially pinpoint the number of vulnerable targets and design a drug that would interfere with a particular function of a gene or a gene product like a protein.

The other falls under the category of what we call structural biology where you can actually make a map of the structure of the virus and interfere with certain important components of it. One typical example is the drug CD4 which is a soluble form of the receptor for the virus. So, if you flood the system with CD4, you essentially block the ability of the virus to ultimately interact with the receptor on the cell.

There are a number of peptides, very interesting peptides, that can block binding. In fact, one is being actively pursued by the

group that Dr. Goodwin directs. He might want to make mention of some of the neurological aspects of structural biology.

NEUROLOGICAL CONSEQUENCES OF AIDS

Dr. GOODWIN. One of the biggest problems with AIDS, of course, is that it alters the brain. In fact, one of the problems with getting people to change their behavior is that they begin to have mild forms of dementia and mild forms of psychosis. So they can't remember or can't follow what it is they are supposed to do. Thus, potential change in sexual behavior or drug-seeking behavior is, in effect, somewhat cancelled by the changes that the virus induces in the brain.

One of the things we have been working on is testing some neuropeptides that appear to interfere with the ability of the AIDS virus to affect the brain. One of them is called peptide T, another one is called peptide H.

But I think, as Dr. Fauci suggested earlier, the ultimate treatments for AIDS might involve a mixture of drugs, some targeted specifically at the immune system, some at the virus itself, and some at the brain and other infected organs.

IV DRUG ABUSERS AND AIDS

Senator HARKIN. Dr. Goodwin, as long as I have you at the microphone, I wanted to cover with you basically what is happening with the IV drug abuse population. Most of the charts I saw indicate that that is really where the real problem is.

Dr. GOODWIN. It is certainly where the fastest growth of the problem is occurring. And also, as Dr. Noble said, it is the major vector into the heterosexual population. In fact, 70 percent of kids born HIV positive in 1988 are infected as a result of IV drug abuse by the mother or someone with whom she came in sexual contact.

We now know that virtually all IV drug abusers know the facts about AIDS and dirty needles. We have been able to show in our demonstration outreach projects that you can, indeed, get them to listen, and to feed the information back.

But the real question is does that change what is a highly reinforced behavior. As Dr. Noble said earlier, it is not enough to know that something is dangerous. Witness the smoking that people who are addicted to nicotine continue to do even though they very clearly know that this increases their risk of cancer. This is even more true in drug abuse which is a highly reinforced behavior. To get people to change drug abuse behavior takes more than public service announcements and pamphlets that tell them that they are increasing their risk of AIDS.

There are a number of prevention strategies that are beginning to show some positive effects as long as people stay in treatment. But keeping them in treatment is a real challenge.

Senator HARKIN. If you are in that population where you are using IV drugs, for the most part the prospect of getting AIDS may be the least of your worries.

Dr. GOODWIN. Yes; and I think the way you put it pinpoints the fundamental issue in designing treatment and prevention strategies for IV drug abusers. That is one of the reasons why the De-

partment has $900 million in its budget for fighting drug abuse. A fair amount of that is set aside for intravenous drug abuse.

Senator HARKIN. In terms of what? Education, treatment, rehabilitation, what?

Dr. GOODWIN. It is across the spectrum from research to treatment and prevention, and includes block grants to the States.

IV DRUG ABUSE RESEARCH

Senator HARKIN. When you say research in IV drug use, what do you mean?

Dr. GOODWIN. It is critically important to understand better why people abuse drugs. For example, what are the brain mechanisms that cause craving for drugs? We know that psychological and counseling strategies can be applied to get people to make firm decisions to stop using drugs. Nevertheless, when exposed to the environment where they got drugs, or even to anything that reminds them of their drug behavior—like looking at a needle or a syringe. Addicts find an almost insurmountable craving coming back.

We know now from animal and human studies that this craving involves changes in the brain, very much like epilepsy involves changes in the brain. There is among drug abusers, abnormal electrical activity in parts of the brain that control appetite and behavior. A new treatment was recently developed from an animal study using an anticonvulsant to control cocaine craving. That treatment is now in clinical trial, and the preliminary results are quite encouraging.

However, it is not enough to get a new drug treatment into the laboratory or into the clinic. What we must do is apply that research in the real world, for example, in a street clinic in the South Bronx. That's an area where we have a fairly large gap in our knowledge. What our demonstration projects are trying to show is whether what we know from the laboratory can be applied in the real world.

PEDIATRIC AIDS

Senator HARKIN. Let me ask you about another end of research, pediatric AIDS. I have been told by the Pediatric AIDS Foundation that we are not spending enough on basic research for pediatric AIDS.

Dr. Fauci, how do you feel about that, and are there additional opportunities for basic research in this area that we should be concerned with?

Dr. FAUCI. Yes; there are opportunities for basic research and additional research in pediatric AIDS. But I think it is important to point out that basic research on AIDS in general that would seem on the surface to be directed predominantly toward adults has important implications for understanding pediatric AIDS because there are so many things in common between pediatric and adult AIDS.

Also, I would hasten to point out that there are other areas of pediatric AIDS that are unique to children, namely, the fact that the virus is attacking a developing immune system or a developing

central nervous system. So, there really is need for research in pediatric populations.

What we have done at the NIH with regard to research over the past year, is that we have added 11 new clinical trial units to our already existing three to give a total of 14 clinical trial units that are specifically designated for investigations in children.

So, I think we are doing a lot. More needs to be done. We are going to try to do more in the coming year.

Senator HARKIN. I have some more questions on AIDS which we will submit for the record, but now I would like to get into a couple of other areas.

MEDICAL TREATMENT EFFECTIVENESS

A recent survey in my State of Iowa showed that people who live in a city called Fort Madison are 25 times more likely to have coronary bypass surgery than residents of another city called Atlantic. People who live in Webster City are 31 times more likely to be hospitalized for pneumonia than the residents of Osage. Clearly, doctors have different views about the effectiveness of medical procedures.

Your budget proposes $52 million for research on patient outcomes and the medical effectiveness of certain procedures leading to the development of practice guidelines for physicians. This is a $46 million or an 800 percent increase.

I am very interested in this because more and more we see instances just like this where there is this huge difference between what doctors prescribe in terms of hospitalization or level of care in different areas.

Does the Department have a long-term agenda for patient outcomes research, and who is coordinating this?

Dr. DICKSON. The Department does have a long-range plan. Essentially, it extends over a period of 3 to 4 years, and while we are asking in fiscal year 1990 for $52 million, as a rough estimate, I would think that the appropriations required to do the job in this area over a period of maybe 4 to 5 years may be as much as $350 million to $400 million.

The plan itself, in terms of its content, is rather elaborate, but 70 percent of our effort will be looking into the relationship between medical practices and patient outcomes.

The second area we will be accenting will be making more of the data bases that we now have in the Health Care Financing Administration and developing some new data bases.

The third level of effort will be to renew our activities for disseminating the information as we accrue it.

In an organizational sense, it is now under discussion within the Office of the Assistant Secretary for Health as to the exact mechanisms that will be used to operate the program. In the most general sense, we expect in the Public Health Service, that of the $52 million, approximately $43 million will stay in the National Center for Health Services Research for research on this issue. Approximately $7 million to $8 million will go to the Health Care Financing Administration for the purposes of getting the data that we need, and $1 million or $2 million will be in the Health Resources

and Services Administration for the purpose of disseminating the information.

I think beyond the arrangements I have mentioned between the National Center for Health Services Research, the Health Care Financing Administration, and our Health Resources and Services Administration, there is a critical question as to how this expanding activity will be monitored and managed within the Office of the Assistant Secretary for Health, and what it will mean to the present structure of the National Center for Health Services Research. We are in the process of discussing that at this time.

Senator HARKIN. I was just wondering how that is going to effect HCFA Medicare reimbursements. Are you going to make recommendations in terms of how Medicare reimburses and rates services based upon these differences?

Dr. DICKSON. Yes; I might say, because the question does come up, Mr. Chairman, that it is not our intention at all, within the Public Health Service, to develop some set of standards that practicing physicians should follow in the future. Rather, we look on our activity as a risk assessment activity where we provide the information to physicians, to patients, to employers and insurers, and to HCFA for them to make their own determinations in a management sense.

Senator HARKIN. Thank you all. Those are all the questions I have for this panel.

I see we have been joined by the distinguished Senator from Arkansas.

Senator BUMPERS. You are mighty nice to notice, Mr. Chairman.

Senator HARKIN. I was just about ready to move on to the next panel, unless you have some questions for the panel. We just had a great presentation on AIDS.

Senator BUMPERS. I got the whole dose during a recent visit to NIH. [Laughter.]

Senator HARKIN. Thank you very much, Dr. Dickson and all of you.

ORGANIC TREATMENTS FOR AIDS

Senator BUMPERS. One thing on AIDS. Did you cover the story this morning about the Chinese cucumber root?

Dr. FAUCI. No; we didn't cover it, but I can give you a 10-second——

Senator BUMPERS. What do you know about it, doctor?

Dr. FAUCI. It is an extract from the cucumber root that has been evaluated in the test tube and shown to kill HIV infected cells. I think it is important to point out that there are a number of compounds which, in the test tube, are shown to have activity against HIV.

One of the problems is that the public reads an article like that, and they immediately think there is a new, highly promising drug that is imminently going to be available to people. In fact, the compound hasn't even been used in animal studies and certainly not in human clinical trials.

So, it is interesting to see yet again another compound that is able to kill, in vitro, an HIV infected cell, but there are many,

many compounds that can do that. The real trick is if it can be done in a nontoxic way when given to humans.

Senator BUMPERS. As far as you know, there isn't anything different about this compound than others that do the same thing?

Dr. FAUCI. Well, the mechanism of how it does it has not yet been worked out. There is some suspicion that it blocks ribosomes within the cell that are important for cell function. But other than that, the real mechanisms of action have not been delineated.

OTHER IN VITRO AIDS TREATMENTS

Senator BUMPERS. Are we doing human tests on others that have proven effective in a test tube?

Dr. FAUCI. Oh, certainly. That is, in fact, the first step toward all of the 27 agents that are currently in clinical trial right now in our clinical trial units. They all started by showing activity in the test tube, and then they move on either into animal studies and then to man or, in certain cases, directly into man.

Senator BUMPERS. One protocol that you had when I was there was one that built a shield around the AIDS virus so that it couldn't replicate itself. Is that not correct?

Dr. FAUCI. Well, that is a compound or molecule called soluble CD4 which binds to all of the binding sites on the virus and prevents it from sticking on the cell. The ultimate result is that the virus cannot enter the cell that it needs to replicate. So, the end result is that the virus will not be able to propagate itself.

Senator BUMPERS. How is that going?

Dr. FAUCI. The trials using soluble CD4 are in a phase one stage in which we look for toxicity and proper dose. They are moving along very well. There doesn't seem to be any untoward toxicity that might prohibit us from going to the next step. So, we are cautiously optimistic that this may be one of the drugs in the armamentaria that we will be able to use against HIV.

Senator BUMPERS. Are you still using AZT as routine treatment of AIDS patients?

Dr. FAUCI. Right now that is the only approved treatment for HIV infection. Alpha interferon has been shown to be effective in patients with Kaposi's sarcoma, but AZT is still the prototype index drug.

AIDS RESISTANCE TO THERAPEUTICS

Senator BUMPERS. I saw a story the other day that said HIV is mutating, and that AZT is not as effective as it once was. Is that an accurate story?

Dr. FAUCI. Partially accurate. What is happening is that it has been demonstrated in the test tube that resistance to AZT has developed. Whether or not that is going to turn out to be clinically relevant is unclear. There was no correlation between the development of resistance in the test tube and someone not responding to AZT clinically.

Now, if in fact resistance that is clinically relevant does occur, that is not surprising because we have seen the emergence of resistance to drugs in a number of microbes, bacteria, viruses, and

fungi. This occurs by adaptation to a particular drug either by mutations or some other sort of adaptation.

The way you get around that is that you either develop new alternative drugs or you use combinations of drugs. Infectious disease experts and microbiologists have been battling drug resistance for decades now. When penicillin first came out, everything was sensitive to penicillin, and now there are a number of resistant strains for which you develop other drugs. We predict this is what is going to happen with the AIDS virus, that resistance will develop and then other drugs will take the place of the drug to which the virus is resistant.

Senator BUMPERS. Thank you, Doctor.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you all very much.

Dr. DICKSON. Thank you, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

AIDS - GENERAL POPULATION

Question. AIDS continues to be number one health priority but still there seems to be some reason for optimism. The new infection rate among gay men has come sharply and is now less than 1 percent. The HIV infection rate among military recruits and blood bank donors has come down slightly in the last year. The HIV infection rate among Job Corps applicants and those admitted to the group of hospitals CDC is tracking has been flat over the last year. The Department continues to estimate that between 1 to 1.5 million Americans are infected with the virus. Dr. Noble, what do you consider to be the likelihood of AIDS spreading widely into the general population?

Answer. There is no doubt that HIV can be transmitted through heterosexual contact, both from men to women and from women to men. At present, most of the heterosexual transmission that is occurring appears to be from IV drug abusers to their sex partners. The presence of sexually transmitted diseases that cause genital ulcers also greatly increases the risk of HIV transmission, if either partner is infected with HIV. There appears to be limited spread into other groups of sexually active persons at the present time.

AIDS INFECTION RATE

Question. I understand that in New York City, one out of every 61 babies born is HIV-positive. In inner city hospitals in Baltimore and Newark, the infection rate among emergency room admissions is 5.3 percent. Does this high infection rate in these inner city populations suggest that HIV infection may well spread across the nation or are these populations fairly contained?

Answer. These studies do suggest relatively high HIV infection rates in selected inner city populations. They are not representative of the entire nation. However, the potential for heterosexual spread of HIV does exist in settings where there are infected HIV drug abusers, where sexual activity is high, and where other sexually transmitted diseases, particularly syphilis and chancroid, are common.

AIDS EDUCATION CAMPAIGN

Question. Until we have an effective treatment therapy it is predicted that all AIDS patients will eventually die. Our best defense against AIDS continues to be an aggressive educational campaign to prevent people from contracting the disease. Last year we funded an every household mailer that went to 107 million American households. We also are spending $261.9 million this year for various prevention and education efforts. What do we know about the effectiveness of these efforts? Are Americans better educated about the risk of AIDS and how they can avoid contracting the disease?

Answer. One of the most important indicators of effectiveness has been the decrease in sexually transmitted diseases and syndromes associated with homosexual men. This trend

has been observed across the nation for the past 4-5 years. Nowhere has this been more dramatically evident than in San Francisco during the past several years. In this same area, the rate of seroconversions to HIV infection among gay/bisexual men in a large CDC-sponsored cohort study has declined to less than one percent annually.

Reports of knowledge, attitude, and belief (KAB) surveys from all localities suggest increases in AIDS-related knowledge in all risk populations and sectors of society. Some of the survey results also show indications of important behavioral change in groups such as IV drug users. The frequency of needle-sharing is down. Where health agencies are taking education about decontaminating drug use equipment to the "streets," bleach is being much more frequently used. Reports of condom usage show a mixed rate of success among IV drug users and also among other populations where sex is a primary factor of risk for HIV infection. The challenge is closing the gap between knowledge and behavior. Sexually active persons, who do not uniformly use condoms, most often report knowing the risks and recommendations.

Further evidence of effectiveness is provided by the National Health Interview Survey which indicates that 93 percent of those surveyed were aware HIV is sexually transmitted and 95 percent were aware that it can be transmitted through needle-sharing.

In summary, HIV prevention efforts are clearly reaching many people who are receptive to altering their behavior once they know the facts. Those who are less receptive, or who deny their risk, require more specific and highly targeted education. CDC is approaching this challenge in several specific ways by, emphasizing that health department HIV prevention programs need to work as closely as possible with drug abuse treatment agencies at the local level; supporting an expansion of partner notification efforts to reach those persons who are at exceptional risk; encouraging State HIV prevention programs to expand current levels of support for community-based organizations (over 500 now funded); and, direct funding of community-based organizations in heavily affected areas. Each of these programs is designed to reduce risky individual behavior and to reduce further spread of HIV.

TREATMENT OF AIDS PATIENTS

Question. Are we prepared across the country to provide treatment for the ever increasing number of AIDS patients?

Answer. Yes, at this stage in the HIV epidemic communities across the country are, for the most part, providing the medical and social services that are needed. However, as the numbers of infected people increase, as the populations affected change, as the treatments and services needs change, and as the total cost of HIV services increase, community-based health care systems will face new challenges related to the HIV epidemic.

The Health Resources and Services Administration (HRSA) has designed its current HIV programs to help communities successfully meet those challenges.

The community-based and pediatric Service Demonstration Projects help metropolitan areas with high numbers of AIDS cases to deliver HIV services in a cost effective manner by emphasizing the use of less expensive alternatives to inpatient hospital care (i.e.; outpatient, long-term, home health, and respite care) and by organizing patient care through care management techniques. In FY 1989, a complementary program for HIV Services Planning will help States, Territories, and metropolitan areas with projected high numbers of AIDS cases to plan for and organize HIV services.

The Education and Training Centers program is designed to train primary care providers to diagnose, manage, and treat AIDS patients.

The AIDS Facilities Renovation program provides financial support for building and renovating non-acute, intermediate, and long-term care facilities for care of HIV infected patients.

TREATMENT DEMONSTRATION

Question. The Department has requested $18.8 million to continue the existing demonstrations.

Needless to say, these grants have assisted communities in developing service delivery systems and was important early on because large AIDS caseloads left many communities without the time or resources to develop an appropriate response. It is my understanding that these demonstrations were not intended to be permanent.

How long will it be necessary to continue these demonstration grants?

Answer. It is difficult to predict just how long it will be necessary to continue these demonstration grants. For the immediate future, federal assistance to enhance HIV services, including service demonstration grants, will be needed to help cities develop effective ways of dealing with the rapid growth and changing character of the HIV epidemic, with difficult service development and coordination problems, and with newly available therapies, including new expensive drug therapies.

At the outset, the epidemic affected primarily homosexual and bisexual men. There were no effective drugs or therapies to treat HIV infection, and care was given primarily in acute care settings. In this period, the emphasis of the service demonstration projects was on developing alternatives to hospital inpatient services and effective ways to link services to improve the continuity and quality of care. While a more appropriate array of services now is available to HIV-infected people in many communities, further efforts are needed to develop certain services: especially long term care and residential care, better linkages among an increasingly complex set of services and providers, and ways of dealing with deficiencies in the financing of serious chronic illness.

Currently, the HIV-infected populations growing most rapidly are intravenous drug abusers, women, and children, most of whom are members of racial or ethnic minorities. The service needs, social

support systems, cultural characteristics, outreach needs and financial resources of these populations are very different from those faced earlier by most service demonstration projects. New approaches need to be developed to increase access to services and linkages among services for these populations.

Finally, sharp increases in the number of people with AIDS and HIV infection require development of service delivery networks on a much larger scale. New approaches are needed to coordinate services and deal with the inability of volunteer-provided support services to handle much larger infected populations in the cities that received early service demonstration grants. Additionally, cities with service delivery and financing systems substantially different assistance to develop suitable HIV service networks.

AIDS - FAMILY OF SURVEYS

Question. Last year the Committee provided $57.9 million for a family of surveys to better understand the actual infection rate among the American population. Dr. Noble, what can you tell us about findings to date?

Answer. The family of surveys, comprised initially of a limited number of serologic studies, surveys, and analyses of HIV seroprevalence data from sentinel hospitals, blood donors, and civilian applicants for military service, has developed into a broad mix of nationally conducted population and clinic-based serologic surveys and studies that are now beginning to provide critically needed data. These focused surveys and studies, each highlighting a different element of the HIV/AIDS epidemic, are continuous or recurring at annual intervals to permit monitoring of trends, as well as, levels of HIV infection in the various groups at risk.

Implementation of the family of surveys represented a new kind of national surveillance effort in response to the HIV/AIDS epidemic. The surveys have been implemented incrementally, and data will become available as study sample sizes are reached (1,500 eligible specimens from STD, 1,000 for women's health, 600 for IV drug abuse, and all available specimens from tuberculosis clinics). Because of differences in the availability of eligible specimens from site to site, some areas will require longer to complete the individual surveys than others. As of April 1, 1989, preliminary data from 22 clinics and neonatal data from 9 areas had been received at CDC. When complete data are received, they will be assembled in various charts, graphs, tables, and texts for dissemination (in full collaboration with cooperating health departments).

Over time, as trends of infection in the various groups being surveyed become clear, it will be possible to know more precisely where prevention efforts should be directed and how to guide the public health response.

CDC has confirmed the enormous diversity of impact of HIV infection by geographic area, urban vs. rural residence, age, gender, race/ethnicity, and by behavioral patterns. CDC has also learned that there is considerable enthusiasm in State and local health departments for developing data to assess and monitor the

patterns of HIV infection in their areas of responsibility to aid in targeting and evaluating prevention programs. CDC has expanded its efforts from the initial 30 cities in 24 States and territories involved in the family of surveys in 1988 to include 39 cities and 44 States and territories involved in the family of surveys and neonatal HIV surveillance. CDC has also learned that simply conducting the surveys has had a major impact by showing health department and clinic personnel that HIV really occurs in the populations they serve. This has made the epidemic more "real" and immediate to the public health and clinical communities in the areas involved in the family of surveys.

AZT

Question. Dr. Fauci, I understand that NIH has had a clinical trial underway for one year testing whether or not HIV infected individuals should start using AZT before they actually contract AIDS. I understand that many HIV positive people already do use AZT and are not waiting for the results of your trial. When do you believe NIH will be prepared to announce the findings of this trial?

Answer. The protocol to which you refer, ACTG 019, is a double blind, placebo-controlled study of AZT in asymptomatic HIV infected individuals. The target sample size for this study is 3,200 patients. We have currently entered a little over 2,900. The expected duration of the trial must take into account the rate of patient entry and the number of endpoints that emerge during its course. It is likely that the final analysis would not be done until 1991. As with all other such trials, it is subjected to interim monitoring by an independent Data and Safety Monitoring Board (DSMB) to determine whether dramatic differences in toxicity or efficacy have emerged that would mandate early termination. Access to this interim data is limited to the DSMB only so it is impossible to predict when or even if the trial would be terminated earlier than expected. While it is true that some physicians and patients support the use of AZT in this population, there is no data yet to support this hypothesis.

COST OF AZT

Question. With an annual cost of $8,000 to $10,000 a year for AZT; with over one million people for whom it may be recommended; and with the federal government now paying for AZT for roughly one-third of those receiving it, this could be very expensive. If the clinical trial findings are positive, do you expect AZT would be recommended for all HIV positive people or some subset of this group?

Answer. It is not possible to answer this question with anything but speculation, since the outcome of the study is not yet known. It is certainly possible, and many would argue likely, that the study will lead to a recommendation that only a subset of seropositive, asymptomatic individuals receive routine treatment with AZT. Speculating even further, it is reasonable that the specific subset would be those individuals at greatest risk of becoming symptomatic. Again, this answer is not based on data, but only on speculation of one reasonable outcome.

Of course it is important to remember that the expense of treating a group of individuals with AZT could quite easily be balanced or paid for by the savings which could be accrued in health care cost, if only a fraction of the morbidity and hospitalization of full-blown AIDS were prevented.

NIH DRUGS AND THE PRICE OF AZT

Question. Do you expect the development of new drugs will drive down the price of AZT. How much is known about the pricing decision of Burroughs-Wellcome? Are they justified, based on drug development costs, to charge $10,000 a year per patient?

Answer. We have seen a drop in the price of AZT since its approval by the FDA as an AIDS therapeutic. How much further and how long it will take for the price of AZT to drop further depends on the complexities of the private sector which controls this cost. The focus of the NIH is not the cost of AZT, but rather the discovery and clinical evaluation of newer, safer, and hopefully cheaper drugs to treat people infected with HIV. Burroughs-Wellcome has not divulged their costs for developing AZT, so it is not possible to comment on whether or not the price of AZT is justifiable.

AIDS DRUGS AND STRUCTURAL BIOLOGY

Question. Dr. Fauci, over the last year a lot has been reported in the popular press regarding ways to interfere with the viral life cycle based on new understanding of the structure of the virus and how it couples with and invades the healthy T-cells and other cells. Please describe for the Committee progress being made to frustrate the HIV virus' capability to invade and couple with healthy cells.

Answer. Basic research into the structure and molecular biology of HIV has been fundamental to the development of several new drugs that have been designed to block the ability of the virus to invade healthy cells or to arrest virus growth at different stages in its replication cycle. The AIDS virus attaches to the CD4 protein present on the surface of human cells and, once the virus is bound through this protein, enters the cell. One approach is to administer soluble forms of the CD4 receptor(rsCD4) to bind the free viral particles before they can attach to the cell. These soluble forms of CD4 have been prepared using genetic engineering and were shown in test cell systems to trick the virus into attaching to the rsCD4 instead of to the human cells. Currently, three variations of rsCD4 (made by Genentech, Biogen and Smith-Kline) are being evaluated clinically to determine the safety and efficacy of this treatment. Study of the potential therapeutic effect of rsCD4 may yield important new information on the role that this interesting cell surface protein plays in the normal regulation of the immune response. At present, we do not know the exact role that this receptor normally plays in cell function or what signals occur inside the cell after HIV binding.

Due to the affinity of rsCD4 for the virus, this protein is also being evaluated preclinically as a carrier to deliver a toxin, for example pseudomonas exotoxin or ricin, selectively to virally infected cells by attaching to a viral protein, gp 120, present on the surface of infected cells.

Most of the compounds currently used clinically such as AZT and dideoxynucleosides are believed to exert their anti-HIV activity by inhibiting the function of the viral enzyme, reverse transcriptase. Chemical derivatives that act on this enzyme but appear to exhibit less toxicity than AZT for example D4T and azidouridine are expected to enter clinical trials this year.

Other stages in the viral replication cycle are being studied preclinically as potential targets for therapeutic intervention. For example, it may be possible to interfere with the viral genetic message through the use of antisense oligonucleotides so that no mature viral RNAs are formed. Antisense oligonucleotide and ribozymes can also prevent the formation of viral proteins, thus preventing virus particle assembly. Ribozymes which are more potent ribooligonucleotide molecules, are also being tested to see whether they can cause cleavage of viral RNAs. Inhibitors of the genes that regulate expression of the virus are being evaluated as a means to block virus activation. Although not killing the virus, this approach has the potential for preventing the virus from infecting other cells by keeping it in a dormant or latent state. Design of inhibitors of the viral protease, an enzyme that processes the individual proteins used to assemble the virus, also represents a very active research area. Recently, the crystallographic structure of HIV I protease was determined, thus allowing rational design of specific inhibitors. In addition, some drugs are thought to act at the end of the viral life cycle by inhibiting the assembly of viral particles. One or more derivatives of castanospermine, a product of the Australian chestnut tree, will be entering clinical trial in FY 1989. These compounds interfere with the modification of the viral envelope protein. Hypericin, another natural product, also interferes at a late stage in the viral replication cycle. Since these compounds differ in structure and site of action from the nucleosides, they offer potential for improved therapy per se as well as use in combination with current clinical therapies. Combination therapy is used in other diseases to achieve better activity without increasing toxicity.

STATUS OF OTHER AIDS DRUGS

Question. Dr. Fauci, I understand we are funding 45 AIDS clinical trial units including 13 pediatric units, and that a number of new AIDS drugs are being tested. How many potential new AIDS drugs are now being tested, and describe for the Committee the several that have the best likelihood of being approved for "general use" during the next 12 months.

Answer. In addition to AZT and combination trials that include AZT, a number of additional agents designed to treat HIV infection are now in active trials within the AIDS Clinical Trials Group. These include: AS-101; Ampligen; AL-721; soluble CD4; ddC; ddI; D4T; Dextran Sulfate; Foscarnet; N-butyl-deoxynojirimycin; and Ribavirin. All of these ongoing trials are small, Phase I/II trials and are not designed to demonstrate the efficacy of the agents under study. We are, however, working with a number of pharmaceutical sponsors to design Phase III efficacy trials with several of these agents; ddC, ddI, and CD4. In each case, the new agent would be tested compared to the approved treatment of AZT in late stage patients. Given this background, it should be clear

that it would be unlikely that one of these trials could be initiated and produce data that was compelling enough to terminate a trial early, all within the next 12 months. The actual process whereby the drug would be approved for "general use" would likely first be under the Treatment Investigational New Drug (IND) mechanism and the trial data would have to be analyzed by the FDA for that determination.

AIDS AND IV DRUG USE

Question. What are the best prospects for stopping the spread of AIDS among IV drug users?

Answer. It is apparent that many intravenous drug abusers (IVDAs) are concerned about their risk for AIDS and are taking steps to reduce their risk. However, risk reduction efforts are often inadequate and ineffective, and IVDAs are often inconsistent in protecting themselves and others. As long as they are using illicit drugs, IVDAs are likely at times to find themselves in circumstances where the only available needle is one previously used by others, and adequate means of cleaning needles may not always be available. Elimination of drug dependence is the only long-term protection against AIDS.

While some IVDAs are able to quit on their own, most require extensive, repeated, and prolonged drug abuse treatment to stop. Thus, drug abuse treatment offers the best prospect for stopping the spread of AIDS in this population. However, current treatment capacity is insufficient, and the quality of existing treatment has deteriorated over the past decade due to inadequate funding. To realize the potential of drug abuse treatment in AIDS prevention, treatment capacity must be expanded, aggressive outreach must be undertaken to encourage IVDAs to enter treatment, and the quality of existing treatment must be improved.

Yet, it must be recognized that not all IVDAs will be willing to enter treatment, and some will relapse following treatment. Thus, drug abuse treatment alone is insufficient as an AIDS prevention strategy. IVDAs who continue to use drugs must be helped to reduce their risk. IVDAs and their sexual partners must also be helped to reduce the risk of sexual transmission. From experience we know that simply providing information is seldom sufficient. If IVDAs and their sexual partners are to consistently change their behavior, they will need support and reinforcement. One-time interventions with individuals are of limited value; effective prevention requires repeated contacts.

PEDIATRIC AIDS--IV DRUG ABUSING MOTHERS

Question. There have been 1,460 cases of pediatric AIDS reported as of March. I understand that all the Public Health Service agencies are requesting $113 million in fiscal year 1990 for pediatric AIDS, an increase of $22 million over 1989 and an increase of $42 million over 1988. Is it correct that the rapid growth of pediatric AIDS cases is largely associated with mothers who are IV drug users or the sex partners of IV drug users?

Answer. The incidence of pediatric HIV infection and disease is

increasing rapidly. Infants acquire HIV infection perinatally from their infected mothers. Older infants and children, who were not infected perinatally, received contaminated blood products or blood transfusions.

Of the 1,480 cases of pediatric AIDS reported as of April, 1989, 78 percent or 1,168 became infected as a result of perinatal exposure. This exposure category continues to grow as more and more children are infected by their mothers during pregnancy or shortly thereafter. The remaining transmission categories have stabilized, and in the future virtually no children should become infected by non-maternal routes. Only 18 percent of pediatric AIDS cases are children who were recipients of blood transfusion, blood components, or organ transplants. One-third of the 18 percent are hemophiliacs who were exposed through treatment of their disease. Four percent of all pediatric cases have not been categorized adequately and are, therefore, deemed "undetermined."

Mothers who transmit HIV to children during pregnancy have become infected in a variety of ways; however, 72 percent of the 1,168 cases of perinatally acquired AIDS in children can be attributed in some way to IV drug abuse. Fifty-two percent of the mothers are/were IV drug abusers, and 20 percent are/were sexual partners of IV drug abusers. The remaining 28 percent are distributed across a number of transmission categories, including sexual partner of transfusion recipients, transfusion recipients, and not specified.

PEDIATRIC AIDS--VOLUNTEERS FOR TRIALS

Question. Does the relatively small number of pediatric AIDS cases present a problem in the sense of not having enough children to enroll in clinical trials to test new drugs and treatments?

Answer. The relatively small number of pediatric AIDS patients does result in slower advancements in collecting clinical trial data for protocols involving children, however, this is but one of many barriers researchers face.

Research efforts are also complicated by the fact that the majority of pediatric cases occur in families/women in a lower socioeconomic status who are generally underserved with regard to health care. Such individuals outside of the health care system are difficult to recruit in terms of participation in clinical trials.

PEDIATRIC AIDS--BASIC RESEARCH

Question. I have been told by the Pediatric AIDS Foundation that we are not spending enough on basic research for pediatric AIDS. Dr. Fauci, are there additional opportunities for basic research in pediatric AIDS that you feel we should be pursuing in fiscal year 1990?

Answer. In many ways the AIDS epidemic in children has echoed the epidemic in adults: recognition of the disease in children followed its discovery in adults; research into the epidemiology of AIDS in children has been following advancements in the study of AIDS epidemiology in adults; and treatment with AZT of children with AIDS, appropriately, followed treatment with AZT in adults, after its effectiveness and safety were examined.

While there has been extensive basic research on AIDS that relates to both adults and children, there are needs and opportunities to expand basic research on issues that relate particularly to AIDS in children. These include basic research into the developmental neurobiology of HIV--the effect of AIDS on the developing central nervous system of children. Basic research into developmental immunology, the study of HIV on the developing immune system of an infant or young child, is also needed. Studies are needed on the role of the placenta in transmitting the virus and of therapies to block viral transmission.

PEDIATRIC AIDS--POINT OF CONTACT

Question. Do we yet know when the baby contracts AIDS from its mother--is it before birth, during birth, or after birth?

Answer. At the present time, it is uncertain at what point the transmission of HIV from mother to child occurs. It may occur during the first, second, or third trimester of pregnancy or during the process of labor and delivery. The virus has been recovered from fetuses as young as 13 weeks of gestation according to one case report. Some investigators believe that the so-called AIDS embryopathy argues that transmission occurs early in pregnancy although many researchers doubt the existence of this syndrome. Some senior researchers, arguing by analogy to other viruses such as hepatitis B, believe that transmission occurs near the time of delivery. Several case reports of women who received infected blood after delivery of their infants and who then went on to apparently transmit their infection to their children via breast milk suggest that transmission can occur post-partum.

It is correct to say that the timing of vertical transmission, mother to child, is not yet known. It is also important to note that this lack of knowledge may impede the efficient conduct of therapeutic trials aimed at interrupting mother-child transmission of HIV. Some work is currently underway which may add new and important knowledge to this area of research.

PEDIATRIC AIDS--DIFFERENCE FROM ADULT AIDS

Question. Please describe for the Committee the extent to which the recommended treatments and drugs differ for children with AIDS as opposed to adults with AIDS?

Answer. Any person with HIV disease, or AIDS, will require two basic, but different, types of treatment.

First, patients need to be treated for the primary AIDS virus infection with what is called antiretroviral therapy. This treatment includes the use of drugs which interfere with the ability of the AIDS virus to reproduce and spread throughout the body. AZT is one antiretroviral drug. Researchers have discovered that adults benefit significantly from therapy which involves AZT. It is hoped that other antiretroviral drugs that are developed, and found to be effective and safe in adults, will also be beneficial for the treatment of the AIDS virus in children. Trials of AZT and other antiretroviral drugs in children are currently underway.

Second, AIDS patients must be treated for the variety of other diseases, such as malignancies or opportunistic infections (OIs), which take advantage of the patient's compromised immune system. OIs include lung diseases, bacterial and fungal infections, and a host of other illnesses. A large part of the difference of AIDS in adults as compared to AIDS in children lies in this area. Children acquire different HIV-associated diseases than adults. For example, it is uncommon for children with AIDS to be diagnosed with Kaposi's Sarcoma, a form of cancer, whereas adult males with AIDS acquire this cancer quite commonly. Adults with AIDS experience more severe, often life threatening, cases of sexually transmitted diseases while children with AIDS will acquire unusually serious cases of otherwise normal childhood infections including thrush and measles. As a result of these differences, treatments must be developed for different illnesses acquired as a result of HIV infection in adults and children.

STATUS OF AIDS ADVISORY COMMITTEES

Question. Dr. Dickson, the Department has again requested that all AIDS funding be consolidated in the Office of the Assistant Secretary for Health. This request for consolidation has twice before been rejected by the Congress and I am fairly certain it will be rejected again. Nevertheless we are very concerned that all Department AIDS funding be well coordinated, not only among the various Public Health Service agencies but also with the AIDS programs of other Federal agencies.

For that reason the Committee directed the establishment of an HHS AIDS Advisory Board as well as AIDS Advisory Boards for each of the Public Health Service agencies.

Are all of these advisory boards established and active, and are you satisfied that AIDS activities within the Department are well qualified?

The Committee has been told that the AIDS Advisory Board for the Health Resources and Services Administration is not functioning at this time. Is that correct?

Answer. The Public Health Service (PHS) is in the final stages of establishing five new AIDS Advisory Committees to obtain outside expertise on various HIV/AIDS issues:

- On August 21, 1987, Secretary Otis R. Bowen M.D. established the National Institutes of Health (NIH) Acquired Immunodeficiency Syndrome Program Advisory Committee. It held its first meeting on February 26, 1988 at NIH;

- On May 11, 1988, Secretary Bowen signed the charter formally establishing the Centers for Disease Control (CDC) HIV/AIDS Prevention Advisory Committee. It will hold its first meeting on June 26-27, 1989 at CDC in Atlanta;

- On June 2, 1988, Secretary Bowen signed the charter formally establishing the AIDS Advisory Committee in

the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). The Office of the Secretary is in the final stages of selecting the committee members; therefore, the first meeting of the ADAMHA Advisory Committee has not been scheduled;

- On June 3, 1988, Secretary Bowen signed the charter formally establishing the Health Resources and Services Administration (HRSA) AIDS Advisory Committee. The Office of the Secretary is in the final stages of selecting the committee members; therefore, the first meeting of the HRSA AIDS Advisory Committee has not been scheduled; and

- On February 15, 1989, the Acting Secretary, Don M. Newman signed the charter formally establishing the Food and Drug Administration (FDA) Antiviral Drugs Advisory Committee. A request for nominations was published in the Federal Register with a deadline for response by April 21, 1989.

In June 1988, the Presidential Commission on the Human Immunodeficiency Virus Epidemic submitted its final report to President Reagan. In August 1988, President Reagan issued a memorandum to the Secretary directing the Department to address nine AIDS-related activities. The Department is currently implementing these activities. The Health Omnibus Programs Extension of 1988 (P.L. 100-607) authorizes the establishment of a National Commission on the Acquired Immunodeficiency Syndrome. The Commission is to be comprised of 15 members, five to be appointed by the House of Representatives; five to be appointed by the Senate; and five to be appointed by the President. Of the five Administration slots, the act stipulates that the Secretary of Health and Human Services, the Secretary of Defense, and the Secretary of Veterans Affairs must serve as members. Once the members have been appointed and the Commission is operational, it is anticipated that this Department will play a role in its functions.

It is the position of the Department that AIDS/HIV-related activities are currently being fulfilled by the Advisory Committees and other external bodies that are already in place, or in the process of being put into place.

ANTI-SMOKING EFFORTS

Question. According to the Surgeon General, smoking causes 390,000 deaths each year in the U.S. That's 1,068 deaths each day caused by smoking. Alcohol causes 342 deaths a day. All other drugs combined caused 27 deaths each day. Clearly, in terms of saving lives and countless dollars, anti-smoking efforts should be priority #1. To reach the Department's health goals, we must reduce smoking by 4 percent by 1990.

Other than the activities of the Surgeon General, who has been outspoken about the dangers of smoking and what effort is the Department making to attack cigarette smoking?

Answer. Cigarette smoking is the target of campaigns from a number of sources within the Department's Public Health Service (PHS). They include:

Centers for Disease Control

The Centers for Disease Control (CDC), is the Federal agency charged with protecting the public health of the Nation by providing leadership and direction in the prevention and control of diseases and other preventable conditions and responding to public health emergencies.

CDC has developed and is implementing two smoking education programs in schools throughout the United States. "Growing Healthy" is aimed at students in preschool through grade 7. "Teenage Health Teaching Modules" focuses on teenage students.

CDC is involved in surveillance of smoking behavior through the CDC Behavioral Risk Factor Surveillance System. Under this system, 36 States and the District of Columbia conduct ongoing assessments of the prevalence of key behavioral risk factors that contribute directly to the 10 leading causes of mortality and morbidity.

For the Smoking Among Women and Cessation During Pregnancy Project, CDC has developed a series of problem- and population-specific community intervention guides to assist local health departments apply community intervention strategies.

The Pregnancy Nutrition Surveillance System (PNSS) is designed to monitor the prevalence of nutrition-related problems and behavioral risk factors among high-risk prenatal populations.

The CDC, through State health agencies, is working with communities to prioritize their leading behavioral risks and to alleviate or ameliorate these through risk-reduction interventions. Using behavioral risk factor surveillance data and other information, 75 percent of all Planned Approach to Community Health (PATCH) intervention programs include smoking as a priority problem for risk-reduction.

The CDC's Office on Smoking and Health is the Federal government's principal focal point for tobacco and health activities. Its major activities include:

- Coordinating tobacco education and research efforts within the Department and the Federal government. Serving as a liaison with State and local government agencies, professional organizations, and voluntary health organizations.

- Preparing and disseminating the Department's annual Surgeon General's report on the health consequences of smoking and biennial reports to Congress on smoking and smokeless tobacco use.

- Conducting a national public information and education program on smoking and health, targeted to adults and young people.

- Maintaining a collection of more than 60,000 tobacco and

health studies for use by the research and public health community.

- Conducting research and studies, including the development of surveys to determine tobacco use patterns of adults and teens, and analyzing existing data related to the quitting behavior of the smoking population.

- Staffing the Interagency Committee on Smoking and Health. Mandated by the Comprehensive Smoking Education Act of 1984, this committee advises the Secretary of DHHS on smoking and health issues. The committee, comprised of 25 members who represent various Federal and non-Federal agencies, is chaired by the Surgeon General.

CDC is conducting four research and analysis projects on smoking and health. CDC also conducts research on the causes of work-related illness and injuries. The research efforts related to problems of smoking and clean indoor air focus on work-related hazards and exposure, or interaction, with tobacco smoke.

Health Resources and Services Administration

The Health Resources and Services Administration (HRSA) supports a variety of smoking prevention and cessation activities through its offices. Programs are aimed at specific populations, and several are aimed specially at the HRSA employees.

The Maternal and Child Health program currently provides support to 12 special projects of regional and national significance that include smoking as a risk behavior. Ten projects in the prenatal program include smoking as one of the risk behaviors. Another project that emphasizes decreasing risk behavior in adolescents includes smoking as one of the nine risk behaviors.

In the area of health professions and nursing education, many of the grant supported activities in curriculum development, demonstration, and training for health care delivery include smoking as a part of the health promotion aspects.

Indian Health Service

The Indian Health Service (IHS) promotes the practice of healthy lifestyles in American Indian and Native Alaskan communities. The IHS provided a model for Indian communities by making all IHS facilities smoke-free. The IHS set a goal to make non-smoking the social norm, and reduce all opportunities for the consumption of tobacco.

The National Institutes of Health

The National Institutes of Health (NIH) is responsible for the scientific investigation of health problems facing the Nation. Of the nine Institutes, three reported programs directly related to smoking and health:

- The National Cancer Institute (NCI), Smoking, Tobacco, and Cancer Program (STCP), within the Division of Cancer

Prevention and Control (DCPC), serves as the focal point for the NCI's research, disease prevention, and health promotion activities related to tobacco use and cancer. In Fiscal Year 1988, the STCP has allocated more than $39 million to activities for controlling smoking and tobacco use. The majority of these funds will be used for intervention and prevention initiatives. The primary objective of the STCP is to decrease the incidence of cancers caused by, or related to, smoking and the use of other tobacco products. The programs of the STCP may be summarized within five broad categories: basic research, intervention initiatives, target population initiatives, information dissemination and research applications, and surveillance.

The NCI's Office of Cancer Communications (OCC), through its press activities and answers to public inquiries, responds to questions about its tobacco research and control programs and the overall tobacco problem. The NCI assists journalists and health professionals in preparing accurate reports on tobacco-related issues. In its Cancer Prevention Awareness Program, the NCI uses a variety of information and educational approaches to motivate Americans to avoid the use of all tobacco products.

- The National Heart, Lung, and Blood Institute (NHLBI) has the primary responsibility for the scientific investigation of heart, blood vessel, lung, and blood diseases. The NHLBI Smoking Education Program was created to reduce smoking-related cardiovascular and pulmonary disease by developing and marketing educational materials and programs for physicians, other health care providers, and specialized patient populations. The program emphasizes the importance of clinical opportunities; i.e., unique "teachable moments" when an intervention by a physician or other health care provider can have a profound effect on a smoker's behavior.

- The National Institute of Child Health and Human Development (NICHD), Office of Research Reporting, prepared and distributes the brochure "Facts About Pregnancy and Smoking." The Institute is setting up a smoking intervention program for pregnant women, which will be implemented by obstetricians and other primary care providers during patient visits. The project is being implemented in collaboration with the American College of Obstetricians and Gynecologists (ACOG).

Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)

- The Office for Substance Abuse Prevention (OSAP) has developed materials and messages designed to reach pregnant and nursing women, youth, and those who may influence their behavior, as well as health care providers, educators, and parents. The messages are broad; counseling viewers and readers on the dangers associated with alcohol, tobacco, and other drug use.

- The National Institute on Drug Abuse (NIDA), in the mid-1970s, was assigned a leadership role by DHHS in the investigation of the behavioral aspects of tobacco use, particularly addiction to, and dependence upon, cigarette smoking. The results of NIDA-sponsored research have been reported in a series of research monographs, in the second Triennial Report to

Congress on Drug Abuse and Drug Abuse Research (1987), and in the Surgeon General's Report on Nicotine Addiction (1988). Most recently, NIDA published a compilation of research results and guidelines in Monograph Number 48, "Measurement in the Analysis and Treatment of Smoking Behavior", which addresses some of the basic and applied research questions related to smoking and tobacco use.

Office of Disease Prevention and Health Promotion

The Office of Disease Prevention and Health Promotion (ODPHP), within the Office of the Assistant Secretary for Health (OASH), coordinates all prevention activities of the PHS.

As part of its Workplace Health Promotion Initiative, ODPHP commissioned and disseminated two reports on worksite smoking, "A Decision Makers Guide To Reducing Smoking At The Worksite, "produced in cooperation with the Office on Smoking and Health, and the "National Survey Of Worksite Health Promotion."

Summary

Smoking and health is one of the priority areas for the 1990 Health Objectives for the Nation. Work is currently underway to develop a revised set of objectives targeted on the year 2000, and "Reduce Tobacco Use" again will be the subject of a priority concern in that new decade-long health promotion and disease prevention strategy.

MEDICAL TREATMENT EFFECTIVENTESS INITIATIVE

Question. A recent survey in my home state of Iowa showed that people who live in Fort Madison are 25 times more likely to have coronary bypass surgery than residents of Atlantic. People who live in Webster City are 31 times more likely to be hospitalized for pneumonia than residents of Osage. Clearly, doctors have different views about the effectiveness of medical procedures.

Your budget proposes $52 million for research on patient outcomes and the medical effectiveness of certain procedures, leading to development of practice guidelines for physicians. This is a $46 million or 800% increase.

Does the department have a long term agenda for patient outcomes research? Who will coordinate the research, and how many years of research are planned?

Answer. Yes, the Department has a long-term agenda for patient outcome research. The Public Health Service (PHS) will be coordinating the research effort. Over the next ten years PHS plans to:

- o Evaluate the relationship between medical practices and patient outcomes (70% of the total costs of the program), including support of assessment teams and individual investigator-initiated research projects;

- o Identify and assemble databases and improve research methodologies necessary to evaluate patient outcomes (20% of the total costs), including support for basic methodological research in clinical decision making and patient outcome assessment, developing and maintaining person-specific and setting specific data on diagnostic, therapeutic and palliative procedures, and developing improved measures of patient outcome; and

- o Develop and demonstrate mechanisms to disseminate and encourage adoption of this clinically useful information (10% of the total costs).

The Medical Treatment Effectiveness initiative is a multi faceted approach designed to address the complex components of health care delivery today. The program will include both short- and long term analyses, retrospective as well as prospective studies, and will rely upon multiple methodologies to assess the various aspects of physician practices.

There are three basic approaches to the efforts to improve the scientific basis of medical decision-making through this initiative:

- o Research on patient outcomes and clinical effectiveness to continue assessment of the efficiency and effectiveness of particular treatments through patient outcome studies, Peer Review Organization (PRO) participation, data analyses, assessment teams, and special research (e.g., small area analysis, epidemiological research, and clinical trials). These activities will be conducted principally by NCHSR;

- o Collection, development, and analysis of data to expand data available for analysis and improve the ability to link Medicare files to other data bases with information on additional populations. This activity will be conducted principally by HCFA and NCHSR; and

- o Dissemination and assimilation of findings, to disseminate results through journal publications and information networks, incorporation of findings into academic curricula, continuing education and other educational programs. This effort will develop improved methods for disseminating information, and will incorporate findings into health care providers' practice patterns. Payment systems also will be encouraged to reflect research findings. The Health Resources and Services Administration (HRSA) will play a key role in this effort, although HCFA, NCHSR, and other Public Health Service (PHS) agencies will have related activities.

The FY 1990 request of $52.0 million will be managed and controlled by the Public Health Service. Funds will be transferred to NCHSR, HRSA and HCFA via Interagency agreements. Of the $24.0 million requested in budget authority, we currently plan to spend $18.2 million (76%) on research, $4.8 million (20%) on data activities will be transferred to HCFA, and $1.0 million (4%) on information dissemination. An estimated distribution of the resources is as follows:

	($000)		
	FY 1988	FY 1989	FY 1990
Budget Authority			
Research	---	---	$18,200
Data	---	---	4,800
Information Dis.	---	---	1,000
Subtotal	---	---	$24,000
Medicare Trust Funds			
Research	$1,915	$5,879	$25,200
Data	---	---	2,800
Subtotal	$1,915	$5,879	$28,000
Total Obligations	$1,915	$5,879	$52,000

Question. How do you propose to develop the practice guidelines for physicians and how do you hope to have them used?

Answer. The Department is not proposing to establish medical practice guidelines through this research initiative. One of the major goals of this research effort is to help both doctors and patients make informed choices. It is intended to demonstrate that physicians will voluntarily change their behavior when informed about scientific patient-outcome research findings and about treatment patterns in their own market areas. Several NCHSR supported studies have already demonstrated that this is the case.

Dr. Jack Wennberg (Dartmouth University) in his NCHSR supported assessment of prostatectomy, showed that physicians, when faced with the dilemma that stem from a lack of understanding of the outcome implications of their daily practices, are willing to recognize their uncertainties and take the necessary steps to clarify the implications of unassessed theory.

Question. What plans do you have to involve Medicare and Medicaid in the effectiveness research--proposed HCFA regulations published January 30th seem to indicate that effectiveness studies will affect payment decisions. Will they?

Answer. Although FY 1988 was the first year Congress provided funding for the Patient Outcome Assessment Research Program (POARP), NCHSR began the POARP initiative in FY 1987, the first year of authorization. Even though no funds were appropriated specifically for support of the program three research studies were supported out of NCHSR general extramural research funds.

In FY 1988, $1,915,000 was transferred from the Medicare Trust Fund to NCHSR, and used to support a total of thirteen studies which only began to scratch the surface of this multi-faceted issue.

In FY 1989, $5,879,000 was appropriated to the Medicare Trust Fund and transfered to NCHSR to continue and significantly expand this activity. NCHSR plans to use these funds as follows:

- o Continuation costs for the studies begun in FY 1987 and FY 1988 total approximately $1.9 million; and

- o $4 million has been set aside to support four Assessment Teams to conduct in-depth multidisciplinary studies of significant or controversial patient outcome issues. At the present time, we are aware of 15 applications, all of high quality, which have been submitted in response to the Assessment Team program announcement which was released in November 1988. These applications represent geographically dispersed health services research centers of excellence.

The current plan is to continue and extend the Assessment Team approach and to support complementary research investigations to expand the knowledge base with regard to patient outcome assessment in the following areas:

- o assessments of the appropriateness of admissions and discharges;

- o assessments of the extent of professional uncertainty concerning treatment effectiveness;

- o development of improved methods for measuring patient outcomes;

- o evaluation of patient outcomes;

- o evaluation of the extent to which dissemination of the findings of this research to physicians and Peer Review Organizations, (PROs) can affect physicians' practice patterns; and

- o working on reorganization of Medicare data files relating to claims under Parts A and B to facilitate patient outcome research.

RURAL HEALTH RESEARCH AGENDA

Question. In FY 87, this Committee instructed the National Center for Health Services Research (NCHSR) to develop a five-year agenda for rural health services research. We received the preliminary agenda last year, and provided $500,000 for rural health research at NCHSR. Last month we got the final agenda, a detailed list of research questions about rural hospitals, maternal and child health, rural elderly, poor, and uninsured, and other questions we must answer in order to get a handle on the rural health crisis. It looks great.

I don't understand why there isn't any request for funding in FY 90. Does the Department support rural health research?

Answer. Yes, the Department does support rural health research. Congress appropriated $500,000 in FY 1989 to begin implementation of the rural health services research agenda and that amount has been included in the FY 1990 budget request.

Question. What research has NCHSR conducted so far?

Answer. Using intramural data from the National Medical Expenditure Survey (NMES) and the Hospital Studies Program, NCHSR is examining the costs and financing of rural health care. NCHSR has a long history of substantive investment in the development of applied research specific to rural health care needs. Some examples are:

- guidebook for telecommunication technology for rural health care, focusing on the use of telehealth systems for the exchange of patient care data and educational/administrative information (MITRE Corp.);
- development and evaluation of the role of family nurse practitioner services in rural areas (Primex-Frontier Nursing Service and North Carolina);
- development and evaluation of a program of medically trained Emergency Medical Coordinators for small rural communities (Myrick);
- evaluation of the effect of the method of patient payment on the patterns of medical care utilization in a group practice setting in Marshfield, Wisconsin (Broida);
- development of an experimental medical care reviews organization to improve the quality of care, and to contain the cost of medical care in Maine (EMCRO-Maine Medical Association);
- evaluation of the use of former medical corpsmen as assistants to primary care physicians in rural areas (MEDEX-Washington and Utah);
- analysis of the location choices of board-certified medical specialists in rural areas and the effects of changes in their location on the distance traveled by rural population for medical care (and);
- comparative analysis of the use and results of emergency care treatment in rural emergency medical systems with differing levels of personnel training (Stokes);
- analysis of the sizeable effect of the closing of rural hospitals on the economy of the rural community (Christianson);
- study of the relatively small cost savings associated with the removal of beds in small and medium-sized hospitals (Pauly); and
- analysis of the effect of rural hospital closure on the health care needs and limited travel capabilities of the very old population (NCHSR Hospital Studies Program).

In FY 1989 NCHSR is supporting the following extramural research grants concerned with rural health care:

"Health Services Impact of Community Health Centers (CHCs) Use in Rural Maine," P.I. Ronald Deprez, Ph.D., of Medical Care Development, Inc., Augusta, Maine. CHCs are private, nonprofit, fee-for-service health care organizations which provide comprehensive services to residents of rural areas. Some of these centers are located in areas which qualify for Federal reimbursement of costs on the basis of need. Maine has 32 CHCs, of which 18 receive Federal funds.

This on-going study will examine the influence of provider, setting, and patient characteristics on hospital utilization in rural areas in Maine served by CHCs. It also will assess the policy implications of those observations on Federal efforts to provide access to primary care in rural areas. Only the 18 Federally supported CHCs are included in this study. This research is a follow-up to a study conducted in 1984 by Medical Care Development (MCD) in which significant differences were observed in hospital utilization rates between users and non-users of CHCs in rural Maine, suggesting a substitutive effect of CHC use for inpatient hospital care.

"A Study of Access to Medical Care Among the Indigent in Nebraska," P.I.: Keith Mueller, Univ. of Nebraska. This study will: (1) determine the number of medically indigent persons in Nebraska and their geographic distribution; (2) examine the relationship between the economic conditions of the State's 93 counties and the incidence of medical indigence; and (3) identify and compare the problems of access among the uninsured in rural areas with access to care for the medically indigent in urban areas.

The NCHSR's intramural research program also is examining issues relating to rural health care. The National Medical Expenditure Survey (NMES) will provide a unique, updated data base for the analysis of how the population (including rural Americans) uses health care, what they pay for this care, and how we finance these expenditures.

Another component of NCHSR's intramural research program, the Hospital Studies Program (HSP) will analyze comparisons of rural hospitals with their urban counterparts along a number of dimensions, such as environment, service mix, and staffing patterns for all U.S. hospitals. In FY 1988, completed analyses from HSP included "Urban and Rural Hospital Costs: 1981-1985." and "Patterns of Travel for Rural Individuals Hospitalized in New York State: Relationships Between Distance, Destination, and Case Mix."

Findings from: "Urban and Rural Hospital Costs: 1981-1985"

- This NCHSR intramural research study examined trends in rural and urban hospital costs and revenues per admission from 1981 through 1985. The average patient discharge costs for rural hospitals were 40 percent less than for urban hospitals in 1981, the baseline year used for structuring the current hospital reimbursement formula under Medicare's Prospective Payment Systems (PPS). By 1985, the ratio was still the same.

- The study also showed that overall revenue for both urban and rural hospitals increased at roughly an equal rate during those 4 years. In fact, the only significant change in cost and income ratios between the two types of hospitals, is that revenue per discharge from Medicare grew at a much faster rate for urban hospitals than for rural facilities after PPS went into effect in 1983.

- In terms of hospital operations, rural hospitals have experienced far-reaching changes since 1981. The findings show, for example, that while admissions and bed days have declined for all hospitals, the decrease has been more severe for rural facilities. Rural hospitals also appear to be shifting to outpatient services at a faster rate than urban hospitals, and to be relying more on outpatient services as sources of revenue.

- The results of this analysis suggest that recent legislative changes in favor of rural hospitals seem to be moving PPS toward a more proportionally even division of revenues between rural and urban hospitals.

Findings from: "Patterns of Travel for Rural Individuals Hospitalized in New York State: Relationships Between Distance, Destination, and Case Mix."

- This study examined the travel patterns of individuals living in rural areas of New York state who were discharged from short-term general hospitals in New York State in 1983. According to the findings, the closure of rural hospitals, combined with the trend to regionalize specialty hospital services, may have implications for the very old populaton in the Nation's rural areas.

- The analysis of distances traveled for hospital care by rural area residents in New York State showed that few residents 75 years of age and older went beyond the county line for care. Most were hospitalized locally. Only 18 percent crossed a county line to get care, compared with 31 percent of those younger than 75. Overall, 29 percent of the State's rural inhabitants went outside their home county for hospital care. In fact, almost two-thirds of this group went to urban medical centers.

Question. What is the budget for FY 90, and what research will be conducted on the rural health services research agenda in FY 90?

Answer. The budget request for NCHSR includes $500,000 in FY 1990 for its rural health research activities.

NCHSR will continue to support the following extramural research grants concerned with rural health care:

"Health Services Impact of Community Health Centers (CHCs) Use in Rural Maine," P.I. Ronald Deprez, Ph.D., of Medical Care Development, Inc., Augusta, Maine. CHCs are private, nonprofit,

fee-for-service health care organizations which provide comprehensive services to residents of rural areas. Some of these centers are located in areas which qualify for Federal reimbursement of costs on the basis of need. Maine has 32 CHCs, of which 18 receive Federal funds.

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Another component of NCHSR's intramural research program, the Hospital Studies Program (HSP), will continue to analyze comparisons of rural hospitals with their urban counterparts along a number of dimensions, such as environment, service mix, and staffing patterns for all U.S. hospitals.

ADOLESCENT FAMILY LIFE

Question. The Adolescent Family Life program is intended to develop effective approaches to care for pregnant adolescents and encourage unmarried teens to postpone sexual activity. In the last three years, the Reagan and Bush Administrations have changed their minds about this program four times.

In FY 1988, the Department requested a budget cut, and said it was beginning a three-year phaseout of the program because effective models had been developed and were being disseminated to the states. The next year, FY 1989, the Department said there had been a change of heart, that no phase-out was planned. But in the FY 90 budget request, we were again presented with a budget cut and a three-year

phaseout plan for Adolescent Family Life. President Bush's budget restored the cut. Does this decision represent a new outlook on the program? Are you thinking of making it a permanent program instead of a demonstration?

Answer. This action reflects the Administration's concern about the problem of teen pregnancy. The Adolescent Family Life (AFL) program is the Department's only program focused exclusively on the problem of teen pregnancy. AFL is unique in that it has the specific mandate to develop strategies for encouraging teens not to become sexually active. For the already pregnant teenager, the program examines fresh approaches to providing the social, educational, and health services necessary to help her complete a healthy pregnancy. Family involvement is strongly encouraged, and adoption is presented as an alternative to teenage parenting or abortion. President Bush's budget revision specifically emphasized the program's work on adoption, a compassionate alternative to abortion, in his decision to restore the Adolescent Family Life Program to its FY 1989 level.

On April 3, 1989, Secretary Sullivan submitted to the Congress the Administration's legislative proposal for Title XX which proposes that the current program be reauthorized for a three-year period.

PHS COMMISSIONED OFFICERS ASSIGNED
TO OTHER FEDERAL AND STATE AGENCIES

Question. Over 670 of the 5,500 Public Health Service's Commissioned Corps are assigned to other Federal and State agencies. However, preliminary work by the Department's Inspector General indicates that the Public Health Service is not being fully reimbursed for its costs when these officers are detailed to work for these agecies (short fall is over $11 million).

I understand that over 12 percent of the Public Health Service's Commissioned Corps are detailed to other Federal and State agencies and that these agencies may not be fully reimbursing the Public Health Service for the services of these officers. With which Federal and State agencies are these officers assigned? Generally, what are their duties and responsibilities when assigned to these agencies and are their assignments of a full-time or part-time nature?

Answer. We understand that the Inspector General has been reviewing the Public Health Service (PHS) policy and procedures for the assignment of PHS Commissioned Officers (COs) outside of PHS. A report has not been issued, so we cannot provide a formal response to the statement.

However, as of February 1989, PHS has assigned a total of 888 PHS COs outside of PHS as follows:

- 227 to the Environmental Protection Agency (EPA);
- 197 to Federal prisons;
- 160 to the Coast Guard;
- 152 to American Indian tribal organizations under the authority of P.L. 93-638;

- o 88 to the Health Care Financing Administration (HCFA);
- o 31 to Saint Elizabeths Hospital;
- o 12 to the Agency for International Development (AID);
- o 7 to the National Park Service;
- o 5 to the Uniformed Services University of the Health Sciences (USUHS);
- o 4 to the National Oceanic and Atmospheric Administration (NOAA);
- o 3 to the Department of Defense (DOD);
- o 1 to the Executive Office of the President; and
- o 1 to the Peace Corps.

Most of the CO assignments are made in accordance with 42 U.S.C., Section 215 (b) which provides in the pertinent part, "Upon the request of ...any State mental health authority, personnel of the Service may be detailed by the Surgeon General for the purpose of assisting such State... in work related to the functions of the Service". Similarly, Section 215 (a) authorizes the Secretary, upon the request of the head of an executive department, to detail officers to that department for duty as agreed upon by the Secretary and the head of the department.

Question. How are reimbursement rates for these assignments determined and when was the last time they were revised?

Answer. The Public Health Service (PHS) has established written policies for the detail or assignment of PHS CO's outside of PHS, including provisions for reimbursement. PHS does obtain reimbursement for cost of salaries and benefits. However, we do not collect or request reimbursement for the unfunded CO retirement or survivor benefits or medical costs for COs, as this is provided annually to PHS through appropriations from Congress.

PHS NEEDS TO CLOSE OUT OLD ACCOUNTS

Question. Over the years, Public Health Service agencies have obligated funds for literally hundreds of activities and projects. In some cases, all of the moneys obligated for a project were not spent; as such, 2 years after the year in which the funds were appropriated with unspent amounts revert to an "M" account until they are deobligated. Preliminary work by the Inspector General indicates that over $107 million in Public Health Service accounts for fiscal years 1984 and earlier has not been deobligated. To help ensure that proper controls over these accounts exist, the Public Health Service needs to take appropriate steps to approve grantees' and contractors' final reports of expenditures so that these funds can be deobligated.

I understand that for a number of accounts, the Public Health Service has obligated more funds than were apparently needed. For example, budget authority totalling over $107 million for fiscal years 1984 and earlier Pubic Health Service accounts has been transferred to an "M" account. Could you tell me why the "M" account balance is so large and what efforts, if any, are underway to deobligated these funds? Could you provide this Subcommittee with a plan for approving grantees' and contractors' final reports of expenditures and subsequently deobligating these funds in the "M" account.

Answer. We have not seen the Inspector General report delineating this alleged $107 million unliquidated balance. However, the $107 million is a relatively small amount in comparison to the billions of dollars the Public Health Service (PHS) has obligated and passed throughout the Payment Management System (PMS) since its inception in 1971 to FY 1984. This unliquidated amount represents the balance of grants and contracts awarded for which final reports of expenditures have not been made or recorded. There are many reasons for this including; incompleted audit reports, grantees that have gone out of business and technical processing has not been completed, audit disallowances have not been totally resolved, or grantees have not submitted final reports of expenditures. In any event, these funds cannot be used except to pay for obligations incurred during their original period of availability. The PHS agencies and PMS staff recently have launched a concerted effort to eliminate these outstanding balances from the system.

Smoking Grants and Contracts

Question. Please provide the subcommittee with detailed historical and current budget information on the funding for grants and contracts made related to smoking, the dangers of tobacco use, and methods of ending smoking.

ANSWER. The following information indicates budget data for tobacco-related awards during fiscal years 1986, 1987, and 1988:

GRANTS (Cooperative Agreements)	FY 86	FY 87	FY 88
Behavioral Risk Factor Surveillance	-0-$	$ 50,000	$ -0-
Smoking Cessation in Pregnancy	376,169	331,587	472,018
Smoking Cessation Program Evaluation	-0-	150,000	-0-
Handbook for Smoking Cessation During Pregnancy	27,500	-0-	-0-
	403,669	$ 531,587	$$ 472,018
CONTRACTS			
National Information & Education	$634,350	$749,214	$ 669,983
Technical Information Support	860,811	190,411	1,275,000

Report Conference and Editorial Support	402,933	897,354	120,000
To Organize and Manage a Data Center on Smoking and Health	-0-	184,993	184,069
1986 Adult Use of Tobacco Survey	-0-	-0-	14,966
Teenage Health Teaching Modules-Growing Healthy - Smokeless Tobacco	-0-	123,575	-0-
	1,898,094	$2,145,547	$$2,264,018
Total Grants and Contracts	2,301,763	$2,677,134	$$2,736,036

Additionally, a portion of funds provided under the Preventive Health and Health Services Block Grant are used for smoking cessation programs.

Following is a brief explanation of the projects listed above:

GRANTS
(Cooperative Agreements)

Behavioral Risk Factor Surveillance - To assist States in accessing adverse health behaviors (including cigarette smoking) associated with premature death and disability in the U.S.

Smoking Cessation in Pregnancy - To develop and implement smoking cessation programs for women attending public health clinic.

Smoking Cessation Program Evaluation - To evaluate a workplace smoking reduction program.

Handbook for Smoking Cessation During Pregnancy - To assist in improving the quality of smoking cessation programs for pregnant women and the quality of evaluation impact.

CONTRACTS

National Information and Education - To conduct a national public information and education program on smoking and health, through development of TV, radio, and print materials.

Technical Information Support - General technical information support and development of the annual Surgeon General's Report on Smoking an Health.

Report Conference and Editorial Support - General editorial and conference support and development of the biennial National Status Report to Congress.

To Organize and Manage a Data Center on Smoking and Health - Statistical support.

1986 Adult Use of Tobacco Survey - The final year of a $1,063,893 contract to assess the prevalence, attitude, knowledge and beliefs about smoking among the U.S. population.

DEVELOPMENT OF RURAL RESEARCH CAPACITY

Question. Does NCHSR have the capacity to provide technical assistance to develop research proposals from rural researchers, or to establish mentorships for rural researchers similar to those used by NIMH to develop research capacity?

Answer. NCHSR's commitment to support health services research on rural issues includes efforts to provide technical assistance to develop the capacity for rural institutions to study rural health care. This technical assistance is taking various forms. For example,

- The principal investigator on NCHSR's grant "Rural Hospital Management Strategies and Viability" is required to share his methods and findings directly with the Rural Health Research Centers funded by the Office of Rural Health Policy in the Health Resources and Services Administration (HRSA). Assistance has included formal participation in discussion with the five Centers about the methodological difficulties of rural health services research.

- NCHSR staff and consultants have worked with individual applicants in Montana, Nebraska, rural South Carolina, and Maine to help strengthen research proposals.

In addition to the extramural grants supported with the $500,000 provided in FY 1989 to NCHSR for rural health care research, NCHSR is supporting the following grant addressing rural health concerns through funds transfered from the Medicare Trust Fund:

"Rural Hospital Management Strategies and Viability," P.I. Stephen Mick, Johns Hopkins University, Baltimore, Maryland. This on-going study will examine the determinants, characteristics, and effects of strategic management responses by rural hospitals to changes in their environment during the 1980s. The results will provide knowledge about relationships between changes in payment systems and local economic conditions during the 1980s, and rural hospital management strategies and economic performance. Evidence about the relative effectiveness of various management strategies may help rural hospitals adapt to their changing environment.

OTHER FACTORS AFFECTING PATIENT OUTCOMES

Question. Patient outcomes is a very broad issue. In addition to medical procedures, outcomes are also influenced by the patient-doctor relationships, where a procedure is performed, and other "environmental" factors. How will you address these factors in research?

Answer. Factors other than medical procedures, such as the doctor-patient relationship, may influence patient outcomes. However, the extent to which these types of variables affect clinical outcomes of care, and how they do so, is not well

understood at this time. It is likely that they are more or less important depending upon a number of circumstances, such as the nature of the patient's problem (e.g. it is probably a more important factor in outcomes of treatment for low-back pain than for gallbladder disease), and that their influence is indirect. For example, better doctor-patient communication would improve patient satisfaction and understanding, thereby influencing compliance with medical advice which, in turn, might influence clinical outcomes.

One problem with addressing these concerns in medical effectiveness research is that the information is generally not available in the large data bases for medical claims, which typically are used to obtain research data. Indeed, even the measurement of physician-patient interaction is poorly developed at this time.

Smaller in-depth studies are called for and NCHSR has supported a number of these over the years. For example, a recently completed study by Dr. Lois Maiman (University of Rochester) and Dr. Marshall Becker (University of Michigan) found that briefly training physicians in techniques to improve compliance, with treatment recommendations made to mothers whose children had ear infections, was effective in achieving greater compliance with doctors' orders. Another study currently under way is examining how improving communication between the physician and both mothers and children can improve patient self-management and the appropriate use of health services.

Like many other indirect influences, such as where a procedure is done, and other "structural" or environmental features of the care provided, the NCHSR will continue to support studies which enhance our understanding of their contribution to patient outcomes. For example, we supported the seminal study by Flood which demonstrated an association between the frequency of performance of a given procedure and patient outcomes. However, we doubt that such individual-level or institutional-level factors can be incorporated in our patient outcome studies under the Medical Treatment Effectiveness initiative. We also doubt whether they should be studied, even if it were possible. Even though they may influence patient outcomes, the primary question in the Medical Treatment Effectiveness initiative is whether, at a macro-level, the procedure itself can be demonstrated to be effective. Variations in effectiveness due to institutional-level and individual-level factors will continue to play a role in the quality of care and patient outcomes and will continue to be addressed by the NCHSR in its ongoing research program.

VALUE OF TREATMENTS ON QUALITY OF LIFE

Question. How will you take into account the value of treatments on the patient's overall quality of life?

Answer. Although much medical research has focused on death and disability, health services researchers have begun to develop methods for measuring quality of life and overall health status.

Health status measures, such as the Rand General Health Survey and the Sickness Impact Profile are being used in studies of the outcomes of health care delivery.

In the work of Dartmouth's Dr. John Wennberg, patients who underwent prostate surgery were surveyed about their symptoms and quality of life before and after surgery. Those who had the most severe symptoms had the greatest symptom relief, although the surgery reduced symptoms for most patients. The value of a particular outcome to the patient, sometimes called its utility, can also be incorporated into the decision models developed under patient outcome research, to help patients and physicians decide on the best treatment for a particular situation.

MEDICAL TREATMENT EFFECTIVENESS INITIATIVE

Question. Please provide the Subcommittee with a detailed agenda of the specific responsibilities of NCHSR, HCFA, and HRSA for conducting outcomes and effectiveness research, collecting data, and developing and disseminating practice guidelines.

Answer. The Medical Treatment Effectiveness initiative is a multi-faceted approach designed to address the complex components of health care delivery today. The program will include both short- and long-term analyses, retrospective as well as prospective studies, and will rely upon multiple methodologies to assess the various aspects of physician practices.

There are three basic approaches to the efforts to improve the scientific basis of medical decision-making through this initiative:

- Research on patient outcomes and clinical effectiveness to continue assessment of the efficiency and effectiveness of particular treatments through patient outcome studies, Peer Review Organization (PRO) participation, data analyses, assessment teams, and special research (e.g., small area analysis, epidemiological research, and clinical trials). At the current time we expect these activities will be conducted principally by NCHSR;

- Collection, development, and analysis of data to expand data available for analysis and improve the ability to link Medicare files to other data bases with information on additional populations. This activity will be conducted principally by HCFA and NCHSR; and

- Dissemination and assimilation of findings, to disseminate results through journal publications and information networks, incorporation of findings into academic curricula, continuing education and other educational programs. This effort will develop improved methods for disseminating information, and will incorporate findings into health care providers' practice patterns. Payment systems also will be encouraged to reflect research findings. The Health Resources and Services Administration (HRSA) will play a key

role in this effort, although HCFA, NCHSR, and other Public Health Service (PHS) agencies will have related activities.

The FY 1990 request of $52.0 million will be managed and controlled by the Public Health Service. Funds will be transferred to NCHSR, HRSA and HCFA via Interagency agreements. Of the $24.0 million requested in budget authority, we currently plan to spend $18.2 million (76%) on research, $4.8 million (20%) on data activities and $1.0 million (4%) on information dissemination. An estimated distribution of the resources is as follows:

	($000) FY 1988	FY 1989	FY 1990 Estimate
Budget Authority			
Research	---	---	$18,200
Data	---	---	4,800
Information Dis.	---	---	1,000
Subtotal	---	---	$24,000
Medicare Trust Funds			
Research	$1,915	$5,879	$25,200
Data	---	---	2,800
Subtotal	$1,915	$5,879	$28,000
Total Obligations	$1,915	$5,879	$52,000

ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

Question. How many demonstration projects do you expect to fund with your revised request, and how many will be new versus continuing?

Answer. We estimate that funding from the proposed request will support a total of 50 demonstration projects in FY 1990. Of this total, $4.2 million will support 33 new awards and $2.0 million will support 17 continuation grants. In addition to the demonstration grants, we estimate that a total of $1.4 million will be used to support the program's research component. These funds will support 7 new and 7 continuation project awards.

Question. The AFL program is required by Title XX of the Public Health Service Act to conduct formal evaluations of its programs. Would you please highlight the main findings of these evaluations and summarize what we have learned since the program began in FY 82.

Answer. We have been pleased with the findings of some of the Adolescent Family Life (AFL) demonstration projects. AFL evaluations have found evidence that some comprehensive care programs can have a significant effect in improving the outcomes for a pregnant or parenting teen and her infant. In addition, evaluation data have shown that AFL prevention projects can change attitudes and values in ways which result in reduced likelihood of teens engaging in early sexual activity. Among the changes are improved teen-parent communication about sexual matters and values, and changed teen attitudes about the desirability and wisdom of engaging in early sexual activity. A cross-site analysis showed

that of 18 care sites, which reported low birthweight information and which have appropriate comparison populations, 61 percent reported a lower incidence of low birthweight than the comparison group, while only 6 percent reported a higher incidence. In a similar analysis of 10 sites which report educational outcomes, 8 reported significant success in returning participants to school, while only one site reported a success rate lower than its matched comparison population. A preliminary report from an ongoing study of adoption components of AFL care projects provides guidance on which factors appear to affect the decision of pregnant teens to decide on adoption. Specific demonstrations with interesting evaluations include:

Postponing Sexual Involvement, a prevention curriculum developed at Emory University with AFL support, has been found to result in substantially fewer participating teens becoming sexually active than in the comparison group. This curriculum has been adopted for use in school districts throughout Georgia, is being used in North Carolina, Florida and Michigan, and is being considered for use in a number of other states.

Evaluation studies of the Family Centered Prevention of Adolescent Pregnancy curriculum developed at Brigham Young University show that students participating in the program score higher on family strengths and on communicating with their parents about sexual beliefs and values.

Sex Respect, a project focused explicitly on promoting teen sexual abstinence, is being demonstrated in schools in Illinois, Kansas, Missouri and Wisconsin. Evaluation of Sex Respect shows that participants have increased support for the value of not being sexually active, feel more strongly that stopping sexual involvement once having become sexually active is possible and desirable, and are more aware of the risks and consequences of engaging in sexual activity.

Tacoma-Pierce County Adolescent Pregnancy Program (TPCAPP) is a comprehensive care program for pregnant and parenting teens. Washington State initially replicated the project in four high risk counties and they were so successful that they are now permanent programs fully supported by the State. Washington is developing plans to implement similar projects in all counties in the State.

USER LIAISON PROGRAM

Question. Legislators in my state and, around the country have contacted me about NCHSR's User Liaison program, which conducts workshops on effective program management for state legislators. You've placed a great deal of emphasis on effectiveness research, yet there is not request for this effectiveness initiative. What are your plans for the User Liaison program?

Answer. Discussions on an individual basis have already taken place between the User Liaison program and State legislators and other State policymakers regarding the level of interest and concern in State governments with respect to our Medical Treatment Effectiveness initiative. As a result of those discussions, a

meeting is scheduled to take place on June 23 in Hartford, Connecticut, that will bring together NCHSR staff, researchers involved with this issue, and State policymakers from New England and other states to explore ways to communicate effectively about these important questions.

Emphasis will be placed on learning what the informational needs of State policymakers are, as well as discussing how existing and future medical treatment effectiveness research can be conveyed to, and utilized by, State governments.

We anticipate that a seminar or workshop will be designed on the basis of the June 23 meeting which can be conducted for State legislators at different sites around the country.

NATIONAL MEDICAL EXPENDITURES SURVEY

Question. The National Medical Expenditures Survey provides us with critical information about health care cost and utilization. The survey is immensely important to policymakers and also to health care researchers, who rely on the data from public use tapes. I understand that the current survey will be finished in July. When do you expect the draft report on NMES to be finished?

Answer. There will be no single report from the National Medical Expenditure Survey (NMES) project. As was the case with a similar project in 1977, literally hundreds of studies will be based on the data set. These formally published studies, such as the report required by the Medicare Catastrophic Coverage Act of 1988 on the use of expenditures for prescription drugs, will be complemented by thousands of informal analyses undertaken for the Administration and the Congress on issues immediately relevant to policymakers.

Question. Once the draft report leaves NCHSR, what guarantee does the Committee have that report will reach Congress timely?

Answer. Most studies prepared by the Department using NMES data are available immediately after they are completed to the Congress and to the research community.

Question. How fast can you put together the public use tapes? What is your timetable for making these tapes available?

Answer. Although the field work for the Household and Institutional Survey components of NMES were not completed until July 1988, two public use tapes have already been completed. The first tape provides a description of nursing homes and homes for the mentally retarded used in the sample frame. The second tape provides information from the first round of the nursing home and homes for the mentally retarded interviews. The next tapes containing information from the household survey should be available by the fall, 1989.

PHS WORKFORCE

Question. The Public Health Service spends almost $13.5 billion each year to protect the health of the American people. To achieve

this mission, PHS must have a highly skilled workforce. Yet PHS has had extreme difficulty over the past decade recruiting and retaining the top-flight researchers, physicians, and upper-level administrators it needs. What steps have you taken to improve the ability of the PHS to attract and retain skilled staff?

Answer. The Public Health Service (PHS) has developed and implemented a plan for the use of the Physicians Comparibility Allowance (PCA) statutory authority in what has been accepted as a model in maNy Federal agencies. The recent doubling in the allowable amounts has been helpful, but is does not solve the problem for all physicians and does not address the problem of our non-physicians.

To address the issue of senior scientific staff, we have developed a legislative proposal that is currently in the clearance process within The Department. We hope that in addition to remuneration issues, we can address some of the other inhibiting factors, such as pension portability, in the proposal.

We also have good experience with implementing new pay setting authorities for nurses and allied health technicians under our new 38 U.S.C. 4107 authority. This has had a positive effect on some areas of nursing shortages at the National Institutes of Health (NIH) but does not address the major problem in the Indian Health Service (IHS).

BOARDER BABIES

Question. Last year, President Reagan signed into law the Abandoned Infants Assistance Act of 1988, which authorized $30 million to help find foster care and adoption opportunities for babies abandoned in hospitals. President Bush has stressed his support for the family, yet there is no request for this in the FY 1990 budget. Does the Administration support this initiative?

Answer: Yes, the Administration supports this initiative. While there is no specific line-item request in the Public Health Service or Human Development Services appropriations, the Department is requesting funds under several authorities, which not only address the issue of providing appropriate care for babies abandoned by parents in the hospital, but also the overall issue of caring for children born with HIV infection, AIDS, and drug dependencies. In FY 1989, the Office of Human Development Services in providing approximately $2.8 million to fund a wide range of demonstration projects that offer models for providing social services to HIV-infected children and their families. It is expected that the same amount will be made available in FY 1990.

PRESIDENT'S COMMISSION ON THE HIV EPIDEMIC

Question. Last year at this time, you said it was too early to outline the Department's evaluation of and reaction to the report of the President's Commission on AIDS. What is your response to Commission's report at this time? Which of the Commission's recommendations will you be implementing immediately?

Answer. In June 1987, President Reagan created an advisory commission to investigate the spread of HIV infection and its end

stage manifestation, Acquired Immunodeficiency Syndrome (AIDS). The Presidential Commission on the HIV Epidemic (PCHE) was given the task of advising the President on the public health issues regarding HIV and AIDS, including medical, legal, ethical, social, and economic impact of the epidemic. On June 27, 1988 Admiral James D. Watkins, Chairman, submitted the Commission's report to the President. It contained 597 recommendations covering all aspects of the epidemic including; incidence and prevalence, patient care, health care providers, basic research, vaccine and drug development, the role of the public health system, prevention, education, societal issues, legal and ethical issues, financing health care, and the global issue of the international response to the epidemic.

The Department of Health and Human Services (DHHS) identified 353, or 59%, of the recommendations as being under the purview of the Federal government, and established the status of their inclusion in Administration policy. The majority of the recommendations with Federal components were within the purview of DHHS, most within the Public Health Service (PHS). As of December 1988, 44.4% (171) of these are completed or ongoing, 17.6% (62) were planned for FY 1989 and another 18.4% (65) are under consideration for FY 1990. DHHS disagreed with 15.6% (55) of the recommendations directed to the Federal government.

In response to PCHE, the President issued a 10-Point Action Plan that was consistent with the major recommendations of the Commission and subsequently issued more detailed directives to heads of Departments. The status of the 9 items contained in the President's directive to DHHS is as follows:

1. The FY 1990 budget request reflects a careful review of Commission recommendations against current activities. The budget request includes funding to assure that the highest priority research, services, and educational programs will be carried out effectively and expeditiously. The National AIDS Program Office (NAPO) is implementing a tracking system to monitor progress toward reaching its goals set forth in the Report of the Second PHS AIDS Prevention and Control Conference (Charlottesville Report) and PCHE.

2. The U.S. Health Summit on HIV Infection, sponsored by the PHS was held in November 1988, and was the first of a series of consensus conferences being held on specific AIDS issues. Following this first conference, a series of 5 regional conferences was planned to address specific issues raised at the summit. The planning for these regional conferences is near completion and the conferences will be taking place between June and November 1989.

Additional meetings address specific issues directed by the Commission:

- "AIDS, Frontline Health Care" was a conference for health care workers held in January 1989 and jointly sponsored by Department of Labor and DHHS. Issues addressed were prevention, treatment, safety, and liability.

- o A series of conferences have been held by the Centers for Disease Control (CDC) on HIV reporting issues and will culminate in a Workshop on HIV Infection Reporting that will take place at the V International Conference on AIDS --Montreal.

3. Multiple agencies within PHS have increased efforts for community-based educational programs. A comprehensive approach to prevent further spread of HIV infection includes direct agency funding to numerous community-based organizations and additional support for such organizations through awards made to State, local and territorial health departments, and the U.S. Conference of Mayors. Included among many of these awards are funds for additional PHS efforts addressing special populations including American Indians, women and children, and young people making decisions about drug use.

4. The Food and Drug Administration (FDA) is coordinating PHS implementation of plans to improve the safety of the blood supply, including notification of transfusion recipients who may have been exposed to HIV, improving laboratory quality and blood bank standards and inspections, and encouraging the use of autologous transfusions.

5. At the request of the President's Task Force on Regulatory Relief, and prompted by numerous recommendations in the PCHE Report, the FDA has developed and implemented a plan to reduce the time required for human testing of drugs for life-threatening and severely debilitating diseases such as AIDS. This proposal was published in the October 21, 1988 Federal Register. It was designed to move promising therapies through research more quickly, and to make those therapies available earlier to patients.

   Other steps to accelerate drug and vaccine development include expansion of the drug screening program conducted by the National Institutes of Health (NIH) to determine whether candidate drugs have anti-HIV properties. The program now has the capacity to evaluate up to 500 drugs per week. NIH is continuing to implement its multidisciplinary plan for AIDS vaccine development through government, industry, and academia.

6. The PHS Technology Management Advisory Board and the DHHS Office of the General Counsel (OGC) completed two reports that reviewed private incentives for developing and marketing HIV products. The PHS Technology Management Advisory Board's report concluded that despite the wide variety of existing incentives for developing AIDS-related products, some additional steps are needed. The OGC's report concluded that liability problems do not pose a threat to research on vaccines and drugs at present, though

the potential for future problems exists. Options were identified for addressing such problems, if and when they emerge. The reports were submitted to the White House in December 1988.

7. The Health Care Financing Administration (HCFA) has begun its evaluation of the nation's health care system. Although most of the necessary information is already available for analysis, some additional research will be carried out in FY 1989.

8. In December 1988, the Secretary of Health and Human Services wrote a letter to all Governors to encourage them to sponsor insurance risk pools for persons with AIDS and to suggest sources of technical information and assistance. He received reports from a number of the States regarding this issue. Further efforts to establish insurance risk pools for AIDS patients will be incorporated into a broader effort to establish risk pools for uninsurable persons with catastrophic illnesses.

9. The Report of the Second Public Health Service AIDS Prevention and Control Conference (Charlottesville Report) was published as a special issue of Public Health Reports in November 1988, and serves as the current PHS plan for AIDS prevention and control.

A detailed list of the individual recommendations under Federal responsibility that were either (A) completed or ongoing,(B) planned, or (C) under consideration as of December 1989 has been provided to the Committe for its file.

AIDS VERSES NON-AIDS BUDGET

Question. As the budget for AIDS increases, the budget for non-AIDS activities is not keeping pace. The President's Commission on AIDS recommended that, while responding to the AIDS epidemic is an urgent public health priority, it should not lead to neglect of other health priorities. And certainly it is the case that we have a greater problem in this country with cancer, mental illness, and a host of other ills. Are you concerned about this? Shouldn't we be?

Answer. The AIDS budget in the Public Health Service (PHS) has grown rapidly increasing from $5.2 million in FY 1982 to $1.6 billion in FY 1990. The overall PHS budget has grown, but not as dramatically. Although AIDS is our number one health priority, there are numerous other health priorities. PHS is, of course, concerned about the proper balance of funding of health activities in order that attention to other health priorities is not hindered. Much of the research effort devoted to HIV, e.g., in molecular biology, has expanded the knowledge base that will apply to understanding and ameliorating other non-AIDS conditions. In the last few years, we have made enormous advances in our understanding of viruses and immunology as a result of HIV-related research. The increased collaboration of activities in the public health and research sectors is also of benefit in seeking solutions to complex

health problems. When resources are limited, difficult choices must be made and priorities set. We cannot do all we would want to do in all health sectors. We believe that the current PHS agenda is balanced, but we need to be diligent in maintaining the right emphases and identifying timely opportunities so as to allocate resources appropriately.

FAMILY PLANNING

Question. There is probably nothing more tragic than a baby born with AIDS. According to CDC, as many as 100,000 women may be infected with the AIDS virus already. Providing contraceptives to an HIV-positive woman is a simple and effective way of preventing new cases of pediatric AIDS, yet there is no targeted family planning program for seropositive women.

I understand that the Department's original AIDS request contained $10 million for Title X projects to expand their AIDS-related activities in areas of high HIV infection rates. The funding would be used to develop strong referral and follow-up linkages between Title X clinics and STD clinics, drug abuse clinics, and homeless shelters. Unfortunately, this proposal was dropped when OMB cut back the AIDS request by $300 million. Do you support increased funding for the Title X program specifically targeted to women in high-risk areas in order to reduce the incidence of pediatric AIDS?

Answer. We believe that Title X clinics play an important role in prevention of sexually transmitted diseases, including HIV/AIDS. Title X clinics provide services to a population which is at considerable risk of infection. Oftentimes, Title X clinics are the sole or primary source of health care for their clients. Although the Title X program has received no additional funds for HIV/AIDS services, many clinics are receiving CDC AIDS funds through their state's AIDS Coordinator's office to provide HIV/AIDS services. Other family planning clinics in high incidence areas are serving as alternative test sites and are being reimbursed for the costs involved.

Question. Do you think this would be a sound and cost-effective prevention measure?

Answer. Yes, provision of disease prevention services in a family planning context offers an efficient and effective means of reaching women who are difficult to reach in other ways and may be unaware of their risk for contracting HIV infection and other sexually transmitted diseases.

Question. Do you support reauthorization of the Title X program?

Answer. The Administration will propose that the Title X program be authorized as a State administered family planning grant program. This will enable family planning services to be provided in a way that best reflects local priorities and standards. It will also facilitate better coordination with maternal and child health programs. This coordination will enable both programs to work more efficiently in addressing the problems of low birthweight and infant mortality.

Question. The FY 1990 budget proposes to change the current Family Planning project grant authority to a State-administered program. You testified that state-operated programs would follow state laws. What about federal law -- how would the Department assure continuity and uniformity among programs?

Answer. The Department's proposal would provide States the flexibility to shape their family planning programs to best meet the needs of their residents. Within this framework, certain Federal requirements would be retained from current law, including the prohibition on funding programs where abortion is a method of family planning, the priority of serving persons from low income families, encouragement of family participation, and the requirement that services be provided on a voluntary basis.

Question. What monitoring and reporting requirements would you include?

Answer. The proposal would require States to provide certain information and certifications as a condition for receiving the grant award. In addition, States would be required to submit annual reports detailing the purposes for which funds were expended, who was served, and the extent to which the State met the goals outlined in its application. These reports would be required to be made publicly available within the State.

Question. How would you obtain data about how the program is operating and how many women are being served? How would you gather sufficient information on program operations to be able to assure the accountability of the States?

Answer. In keeping with the philosophy underlying other State grant programs such as the Maternal and Child Health program and the Social Services block grant, the Department would rely on the State to administer the program with a minimum of Federal oversight. Information on the operation of the program and persons served would be provided through State reports, much as this information is now provided by States and other grantees. In the event that information provided in an application, in required reports or from other sources indicated any irregularities, and such irregularities were confirmed by an audit, the proposal provides procedures for recouping any funds found not to have been expended in accordance with the provisions of the title.

Question. There has been little or no data collected on the Family Planning program since 1983. At that time, about 5 million women were being served by the program. How many women are currently being served under the Family planning program?

Answer. Since 1981, the Office of Population Affairs has supported the data collection and analysis for the National Survey of Family Growth as the best and most efficient way of obtaining information on family planning and family creation trends, not just for Title X clients, but also for clients of other clinics and users of private physician services as well. Data on numbers of persons served by Title X clinics continue to be collected by the Bureau Common Reporting Requirements (BCRR) system. In FY 1988, over 4.3 million women were provided services at the approximately 4,000 clinics supported by Title X.

Question. Funding for Family Planning has been cut $27 million since 1981. How many women have had their services cut since then?

Answer. The Bureau Common Reporting Requirements (BCRR) system provided a total estimate of women served in Title X projects in FY 1981 of 4.1 million. This total dropped to 3.9 million in 1982. The BCRR estimate of women served in FY 1987 is 4.3 million. Thus, by increasing efficiency and making good use of funds from other sources available to the Title X projects, including Medicaid, other Federal grant funds, State funds and patient fees, Title X programs have been able to maintain a relatively steady patient load. Furthermore, according to the Alan Guttmacher Institute, the number of low income women at risk of unintended pregnancy dropped from 9.5 million in 1981 to 7.9 million in 1987, a drop of 16 percent. The number of teens also dropped over this period. Thus, during this time, Title X has been providing services to an increased share of the in-need population.

Question. What is the current status of the proposed regulations to end family planning grant support to grantees that provide abortions or counseling about abortion? What are your plans for implementing the funding ban?

Answer. Four separate suits have been filed challenging the statutory and Constitutional bases for the regulations. In three of the cases (Denver, Boston and New York) appeals decisions are pending. The Department is enjoined from enforcing the regulations with respect to certain grantees under two separate injunctions entered by the district courts in the Boston and Denver cases. In the third case, the District Court in New York dismissed the suit and found that the regulations do not exceed the Secretary's authority and are constitutional. The Department is not enjoined from implementing the regulations with respect to the grantees represented in this case. In a fourth suit the State of West Virginia recently filed suit challenging the implementation of the regulations in that State. The case is before the U.S. District Court in Charleston.

It has been, and continues to be, the Department's position that except where enjoined, we will, where practical, proceed to implement the regulations at the time grant awards are made. We are examining difficult implementation situations on a case-by-case basis and taking action as appropriate.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

Question. What is the rationale for requesting a definite appropriation for the retirement pay and medical benefits for Commissioned officers -- what problems resulted from the indefinite appropriation that has served until now?

Answer. Consistent with overall Federal financial management goals, major efforts have been undertaken towards improving the financial management of all accounts, including retirement accounts. The Office of Management and Budget is moving towards making all indefinite appropriations definite, so that the appropriations can be tracked more closely.

There have been no problems resulting from the indefinite appropriation and the benefits for the commissioned officers would be unaffected by this proposed change in appropriation language.

Question. Have actuarial estimates in recent years proven to be accurate, or have benefits drawn exceeded estimates? Please provide the Subcommittee with a chart indicating the projected benefits versus actual benefits over the past five years.

Answer. During the last five years, the estimates for this account have exceeded the actual benefits paid. However, the Administration's proposals have been to change the appropriation to a definite appropriation and the budget requests have included a reserve fund. The reserve fund proposed has varied from a percentage of the request to a set amount. This has made the difference between the two amounts seem larger than it really is.

The following table displays the original budget estimate to the actual obligations for the past five years.

Fiscal Year	Original Budget Est.	(Reserve Included)	Actual Obligations
1984	$78,883,000	(**)	$73,750,000
1985	86,448,000	($7,859,000)	71,774,000
1986	97,282,000	(16,188,000)	83,157,000
1987	91,282,000	(5,000,000)	84,330,000
1988	94,176,000	(5,000,000)	89,859,000

** In Fiscal Year 1984, no specific reserve fund was requested. However, the appropriation language contained a clause which would have allowed up to $7,500,000 to be obligated against subsequent appropriations.

PEDIATRIC AIDS--BUDGET

Question. I am particularly interested in the budget for pediatric AIDS research. How much will the NIH spend on pediatric AIDS research in FY 89? How much is included in the budget for FY 90? How are the FY 89 funds being spent? Please be specific about basic research and clinical research. What are the plans for FY 90? What was the original budget request from each Institute involved in pediatric research?

Answer. It is estimated that the NIH will spend $50,560,000 in FY 1989 and $66,208,000 is included in the FY 1990 President's budget for pediatric AIDS.

The NIAID intramural and extramural AIDS research programs conduct and support a wide range of basic research on HIV and AIDS. The scientific understandings gained through such basic research on the virus, the viral life cycle, and the immunopathogenesis of HIV are broadly relevant to both the pediatric and adult HIV infected populations.

The NIAID AIDS program supports the evaluation of potential therapies for HIV infection and its sequelae through the AIDS Clinical Trials Group (ACTG), consisting of 46 academic

institutions funded at four separate times since mid-1986. In FY 1988, the pediatric component of the ACTG was significantly expanded from 2 units to provide for 11 additional pediatric clinical trials units; and one additional pediatric unit being funded in FY 1989. With a total of 14 pediatric units operational at 36 distinct treatment sites, the capacity to begin large clinical trials in children with HIV infection is now in place. The FY 1990 budget request for the NIAID AIDS program includes $1.75 million in support for even further expansion of the pediatric component of the ACTG to provide for four to six additional clinical trials units devoted exclusively to this population. In addition, the NIAID AIDS program is sponsoring an epidemiological study of perinatal transmission in collaboration with the National Institute of Child Health and Human Development (NICHD). We expect to spend $20,360,000 in FY 1989 and $28,492,000 in FY 1990 for pediatric AIDS research.

The National Institute of Child Health and Human Development will spend approximately $18 million on pediatric AIDS research in FY 1989 of a total AIDS budget for the institute of $21,393,000. In FY 1990, NICHD is requesting $22 million for pediatric research, of a total AIDS request of $27,129,000. The pediatric AIDS totals of $18 million for 1989 and $22 million for 1990 are broken down in the following manner:

National Institute of Child Health and Human Development

	FY 1989	FY 1990
	(millions)	
1) Prevention	6.2	7.6
2) Epidemiology	6.4	7.9
3) Clinical Manifestations and Pathogenesis	2.7	3.3
4) Therapeutics and Clinical Trials	2.7	3.2
TOTAL	18.0	22.0

The institutes involved in pediatric research are the National Cancer Institute (NCI), the National Institute of Allergy and Infectious Diseases (NIAID), and the National Institute of Child Health and Human Development (NICHD). The FY 1990 original request to NIH for each of these institutes was $170,739,000, $628,557,000, and $50,100,000 respectively. Included in these amounts for pediatric AIDS was $4,500,000 for NCI, $41,100,000 for NIAID, and $41,000,000 for NICHD.

DEMOGRAPHICS OF CLINICAL TRIAL PATIENTS

Question. What is the demographic composition of the patients participating in clinical trials? What efforts are being made by the NIH in 1989 and 1990 to bring that composition more in line with the demographics of those who are contracting AIDS?

Answer. The Institutes conducting AIDS clinical trials are the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI) and the National Institute of Child Health and Human Development (NICHD).

NIAID

The demographic composition of patients currently participating in NIAID ACTG protocols is as follows:

SEX	
Male	91.5%
Female	6.5%
RACE	
White	91.5%
Black	7.7%
Other	0.8%
ETHNICITY	
Hispanic	3.7%
Non-Hispanic	90.3%
IV DRUG USE	
Never Used	89.8%
Current Use	0.4%
Previous Use	9.8%

The underrepresentation of minorities in the AIDS Clinical Trial Group (ACTG) clinical trials is a complex problem that requires a multi-pronged solution. We have established the Community Programs for Clinical Research on AIDS. The primary focus of this program is the development of a new level of government-supported AIDS research by establishment of community-based research organizations. This program substantially enhances the access of minority and other underserved populations to NIAID clinical trials.

The NIAID is presently carrying out a plan to increase minority and other underserved population's participation in the ACTG. The plan involves careful study of six cities--New York, Boston, Los Angeles, Miami, Washington, D.C., and Chicago--to assess the specific issues at each location that interfere with recruitment of underserved populations into ACTG clinical trials. Once these issues are identified a comprehensive plan will be developed to address these impediments.

Minority researchers are being contacted directly by NIAID and encouraged to participate in our effort. Minority researchers have shown great interest in the Community Program; and in the Underserved Populations RFA which will be available later in FY 1989; and in the overall NIAID AIDS effort.

Our existing AIDS Clinical Trials Units (ACTUs) are being encouraged to consider establishing relationships with other facilities that routinely see minority and other underserved patients. Some of the existing ACTUs are considering subunit relationships with minority institutions.

NIAID has appointed senior staff persons into positions in which recruitment of minority researchers and minority patients is a top priority. Additional high level minority staff is presently under consideration for positions in NIAID.

NCI

The National Cancer Institute (NCI) conducts Phase I and limited Phase II trials of anti-HIV drugs in its intramural program. These trials encompass pediatric and adult AIDS patients which receive treatment in the Pediatric and Medicine Branches, respectively, of the NCI. At present, approximately 50-60 pediatric patients are undergoing treatment on several protocols, of which approximately 50 percent are minorities. However, up to 70 percent of new referrals are minorities, with 50 percent black and 22 percent Hispanic. In the Medicine Branch, approximately 80 adult patients are undergoing treatment on several Phase I and II protocols. Twenty-five percent of these patients are minorities, of which 15 percent are Hispanics and 10 percent are black and 10-15 percent are women.

Unlike medical centers whose referral patterns generally reflect their local demographic region, the referral base at the NCI is national because of its Federal funding. For this reason, patients must be referred directly to the NCI by their private physician. The only criteria for acceptance to an NCI study is fulfillment of the protocol requirements. At present, the characteristics of the patients referred to the Pediatric Branch broadly reflects the demographic distribution of AIDS in the pediatric community. For example, the majority of new AIDS cases in the pediatric population are in offspring of infected mothers, most of who are IV drug abusers or their sexual partners and belong to minority groups. The distribution of patients in the adult protocols also generally reflect the demographic distribution of adult AIDS, which is principally a disease of male homosexuals. At present, 20 percent to 30 percent of adults contacted AIDS through IV drug abuse and are frequently minorities. It should be noted that one restriction to the acceptance of IV drug abusers into NCI protocols is that the Phase I studies require that patients not be concurrently abusing drugs.

In summary, the patients in the AIDS trials at the NCI generally reflect the demographic distribution of AIDS in the community at large. However, because of the dedicated research role of the intramural program at the NCI, there has been no specific attempt to increase enrollment of any specific demographic patient group.

NICHD

NICHD is conducting a placebo-controlled clinical trial testing the hypothesis that intravenous immunoglobulin (IVIG) will significantly reduce the rate of serious, life threatening bacterial infection and/or deaths in symptomatic children who are infected with HIV. The vast majority of the children enrolled in this trial, nearly 80 percent, are minority children. This is representative of the fact that although minority children constitute only about 25 percent of the total population of children in this country, they make up more than 75 percent of all children with AIDS.

COMMUNITY PROGRAMS FOR CLINICAL RESEARCH ON AIDS

Question. In FY 1989, the Congress appropriated funds for a program of clinical trials conducted by community based physicians. This program is also authorized in P.L. 100-607. What is the progress of this program? What has been the level of interest from

community providers? What level of funding is anticipated in the 1990 budget request? What level of funding would be needed to fund the anticipated number of qualified proposals? I understand this program is funded through a contract mechanism. Why is the program administered in this manner? Is this mechanism important to the effective administration of this program?

Answer. The Community Clinical Research Section was created in the AIDS Program of the NIAID in late November of last year. On January 17, 1989 we issued a Request for Proposals (RFP) to establish, as a pilot program, the Community Programs for Clinical Research on AIDS (CPCRA). This solicitation is intended to establish a mechanism to deliver administrative and technical assistance to community physicians, community clinics, substance abuse treatment facilities, minority medical clinics or groups of clinicians who care for large numbers of HIV infected persons who wish to become involved in HIV-related clinical projects. Only one month later, February 17, we had received over 700 requests for this RFP, by far, the largest response ever received to any NIAID solicitation. The due date for these proposals was April 17 at which time we received 66 proposals. Peer review of these proposals will take place May 22-26 and thus we do not know the exact number of qualified offerors but early indication is that the medical community response to this program has been overwhelmingly strong and the quality of these proposals is quite high. We expect to award these contracts for the establishment of these pilot programs by late summer.

We have requested $12,000,000 for this program for FY 1990. In addition to expanding the number of different community programs supported beyond those few pilot programs initiated in FY 1989, FY 1990 monies will establish the Community Clinical Research Statistical and Operations Centers. The function of the Statistical Center will be to provide statistical scientific leadership for all community programs supported by the CPCRA. This will include providing biostatistical and methodologic assistance to community clinicians as they develop protocols for the conduct of community-based clinical research projects as well as the entry and analysis of all data collected by CPCRA projects. The operations center will provide all support and administrative services necessary to coordinate and communicate with the community programs supported by the CPCRA as well as coordinate all educational and training components necessary for community clinicians who participate in the CPCRA.

The level of funding needed to support the anticipated number of qualified proposals is difficult to estimate prior to knowing the total number of proposals found technically acceptable by the peer review committee, and prior to additional evaluation by program staff. After such review, we will have the data available to estimate the number of meritorious applications that we will be unable to fund from funds set aside in the FY 1989 and FY 1990 budgets.

The Community Programs for Clinical Research on AIDS will be administered through a contract mechanism. That mechanism was purposefully chosen because it will allow the Government to assist community clinicians in the preparation, planning, and conduct of

community-based clinical research on AIDS, whereas the grant mechanism would not allow the Government to provide such assistance.

As you know, many biomedical research programs supported by NIH are funded through the grant mechanism which allows highly qualified experts and scientists to be supported to perform work which they do extremely well, for which the Government has a specific need. Grant support allows the recipient scientist to do what he or she does best with minimal Government intervention. That mechanism, in fact, places significant limits on the amount of assistance or support which the Government can offer to the grantee. The CPCRA initiative, on the other hand, is designed to provide administrative and technical assistance to community clinicians who are currently providing primary care to persons with HIV infection, and who are also interested in conducting HIV-related research. These clinicians are experts in the medical management of persons with HIV infection, but most of them have never participated in a research study or a Government research program. The expertise needed to administer a clinical research program is significantly different from the expertise which these clinicians possess. For example, community clinicians may have no experience in data collection and quality assurance, or compliance with FDA drug testing procedures and requirements, and may need significant technical assistance to develop scientifically sound clinical research protocols. One of the objectives of the CPCRA initiative is to provide these community clinicians with an opportunity to develop skills necessary to establish and run a clinical research program in a community setting.

PUBLIC LAW 100-607

Question. Has the NIH estimated the cost of implementing the various programs in P.L. 100-607 that are not already included in the budget? How much of an increase above the President's budget request would be needed to fully fund P.L. 100-607?

Answer. We have estimated the cost of implementing the programs in P.L. 100-607. An increase of $68,850,000 would be needed to fully implement the requirements of P.L. 100-607. The increases are in the following activities:

	(Dollars in thousands)	FTE
Non-AIDS Activities:		
1. Center of Geriatric Research and Training..	$3,000	-- 1/
3. National Commission on Sleep Disorders.....	250	-- 1/
Subtotal, non-AIDS increases.....	3,250	
AIDS Activities:		
1. Expansion of International Efforts.....	5,000	5 1/
2. Expansion of Information Services.....	4,500	8 1/
3. Expansion of the National Blood Resource Education Program.....	1,100	-- 1/

4.	Extramural AIDS Construction.....	35,000	--
5.	Centers for AIDS research.....	20,000	--
	Subtotal, AIDS increases.....	65,600	13
	Total, increases all activities.....	68,850	13

1/ These programs are underway within existing program funds, but did not receive additional funds needed for expansion.

COHORT STUDY

Question. The NIAID has been funding for some time the Multi-Center AIDS Cohort Study (MACS). What new data have emerged from this study in recent months? What new areas of research are anticipated in 1990?

Answer. The MACS study was funded in the autumn of 1983 to study the natural history of and transmission patterns of AIDS, soon recognized to be from HIV infection. In the original cohort of 4,954 gay and bisexual men, only men with AIDS were excluded from study. About 36.7 percent of the participants have been shown to have had HIV infection at the time of their recruitment in 1984-1985. Another one percent were probably infected at recruitment, while 5.2 percent have seroconverted in the course of the study. About 55 percent of study participants remain HIV seronegative, with another 1.6 percent whose infection status can not be determined with the laboratory results available. Subjects are volunteers from four cities: Pittsburgh; Chicago; Los Angeles; and Baltimore. A study which is different from the MACS in a number of important ways in methodologic design is the San Francisco Men's Health Study (SFMHS). Data from this separately studied cohort are also providing insights as to natural history and transmission of the virus infection. New areas of study in FY 1990 include continued efforts to enroll minority gay and bisexual men, to develop a pathology protocol to better understand those conditions associated with terminal patients, initiation of early diagnostic tests using the polymerase chain reaction technique, expansion of neuropsychologic and psychiatric studies, and establishment of a smoothly functioning serum and lymphocyte repository through the NIAID.

The MACS and SFMHS both gather detailed sexual behavior data from gay and bisexual men or from their sexual partners.

FTES

Question. In the fiscal year 1989 Appropriation, the Congress provided sufficient funds for 830 FTEs for NIH AIDS activities. The President's budget states that actual FTE levels in 1989 will be 780. Why does the budget reflect 50 fewer FTEs than Congress provided for? What specific activities will be delayed or reduced as a result of this lower FTE level?

Answer. The committee of conference (Conference Report 100-880) agreed that funding provided in the FY 1989 Appropriations Act include $10.5 million in the Office of the Director, NIH, to

support a total of no less than 13,252 FTE positions including an additional 200 FTEs for AIDS research and an additional 150 FTEs for non-AIDS activities. The NIH was issued an FTE ceiling of 13,252, an additional 350 FTEs over the FY 1989 President's Budget level of 12,902. The additional FTEs and amounts to support those positions were allocated, as intended, 200 FTEs for AIDS research and 150 FTEs for non-AIDS activities. The FTE ceiling totalling 13,252 FTEs (780 AIDS FTEs and 12,472 non-AIDS FTEs) have been allocated to the NIH components. The 1989 Column of the 1990 Congressional Justification reflects the level of 780 AIDS FTEs including the additional 200 AIDS FTEs provided by Congress in the 1989 Appropriations Act.

Question. How many FTEs did the NIH request for AIDS in its original request to the Public Health Service? I understand the President's budget assumes only 887. What specific programs will be eliminated or reduced as a result of this cut?

Answer. The request to the PHS was $990.2 million for AIDS and included 1,123 FTEs, while the FY 1990 President's Budget level is $752.7 million and 887 FTEs. The reduction in FTEs from the request level relates partly to the reduction in funds for various programs, particularly in the intramural program. The reduction in funds from the request level also resulted in a decrease in requirements for management of the extramural program and demands for support services. Some of the specific areas reduced from the request include some areas of clinical trials, AIDS centers, vaccine development, studies of pathogenesis and pathobiology of the AIDS virus, and other basic research into various aspects of HIV infections.

Question. While the AIDS program receives a net increase of FTEs for AIDS in 1990, the rest of the NIH has a net reduction. What non-AIDS NIH programs will lose staff as a result of this transfer of personnel?

Answer. The FY 1990 President's budget includes 887 FTEs for AIDS and 12,327 FTEs for non-AIDS activities. The net decrease of 145 FTEs in non-AIDS activities from the FY 1989 current estimate would have a trans-NIH impact and would be achieved through additional management improvement efforts, such as in the procurement area; normal attrition; and the slowing or discontinuance of lower priority efforts.

SENIOR BIOMEDICAL RESEARCH SERVICE

Question. There has been a good deal of attention given to the difficulties affecting recruitment of physicians and scientists to the NIH generally. Does this carry over to the NIH AIDS program as well? Are there specific programs that might make recruitment easier? Are these recruitment problems affecting both intramural and extramural AIDS staffing?

Answer. It is true that the NIH has been encountering great difficulty in recruiting and retaining their senior level scientists. The primary reason for this difficulty is the widening pay gap between Government and the private and academic sectors. Also, the rapid growth in biotechnology has increased the competition and raised the level of compensation for top biomedical

researchers in academia and private industry. In addition, the recruitment and hiring processes are somewhat lengthy, such that by the time we are able to make an employment offer, the selected individuals may already have taken positions elsewhere. To the same extent, these difficulties have carried over to the NIH AIDS program, both intramural and extramural.

A number of steps have been taken or are pending to alleviate overall recruitment and retention problems related to senior level scientists, consequently these steps will also benefit the NIH AIDS program.

In an effort to ease recruitment problems related specifically to AIDS positions, the NIH and OPM have, since June 1988, been operating under an agreement that requires OPM to process "name requests" and to issue a certificate of eligible candidates within 21 days of receipt. In addition, an OPM Job Fair was held on August 26 and 27, 1988, at which a number of qualified individuals presenting themselves for employment opportunities in AIDS were hired.

Any position which is related to AIDS research, and for which OPM approval is necessary (i.e., excludes those for which we have direct hire authority), can be filled under this authority. As such, management and administrative support positions can also be filled under this authority.

To further assist us in recruitment of AIDS staff, the Congress enacted on November 4, 1988, P.L. 100-607, the Health Omnibus Programs Extension, provisions of which grant authority to NIH to request priority approval of personnel allocations for positions and administrative support or space related to AIDS research. The Act also provides that "priority requests" shall be deemed to be approved if not disapproved by OPM/GSA within 21 days of the request.

To implement this provision, the Director, NIH, delegated to BID Directors the authority to submit priority requests to OPM. Operating instructions have been issued to BID Personnel Officers. If situations arise in which OPM does not meet the 21-day timeframe, the Director, Division of Personnel Management (DPM), will review the case before an appointment is effected.

P.L. 100-607 also included a provision that would establish, as a recruitment tool, an educational loan repayment program of up to $20,000 for health professionals who agree to conduct AIDS research when employed at the NIH.

Lastly, the Public Health Service (PHS) has just received authority from OPM to examine and hire biologists, microbiologists, and chemists, grades 9 to 15, without going to OPM. These are the most populous scientific occupations at the NIH, and many positions in AIDS research are filled with scientists with these backgrounds. This new authority will allow the NIH to reduce even further the time needed to hire scientists for these critical positions.

TRAINING

Question. The FY 1990 budget assumes a slight decrease in the number of AIDS training slots for NIH. What will be the long-term

impact of this reduction on the capacity of the research community to address AIDS?

Answer. We have undergone an intense scrutiny of our training program and intend to stimulate training applications in AIDS research with the anticipation of increasing the number of training slots funded in FY 1990. We are committed to increasing the pool of available research talent to avoid a shortfall in trained researchers. This pool of trained researchers is mandatory if we are to remain on the cutting edge of scientific discovery.

CENTERS FOR DISEASE CONTROL

STATEMENT OF WALTER R. DOWDLE, PH.D., ACTING DIRECTOR, CENTERS FOR DISEASE CONTROL

ACCOMPANIED BY:

DR. ALAN HINMAN, DIRECTOR, CENTER FOR PREVENTION SERVICES

DR. DONALD MILLAR, DIRECTOR, NATIONAL INSTITUTES OF OCCUPATIONAL SAFETY AND HEALTH

CLAUDE PICKELSIMER, DIRECTOR, FINANCIAL MANAGEMENT OFFICE

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

DR. MANNING FEINLIEB, DIRECTOR, NATIONAL CENTER FOR HEALTH SERVICES

BUDGET REQUEST

Senator HARKIN.We will now hear from the Centers for Disease Control. Testifying is Dr. Walter R. Dowdle, Acting Director of the Centers for Disease Control, the focal point within the Public Health Service for disease prevention and control.

The fiscal year 1990 request for the Centers for Disease Control is $573,558,000, a reduction of $26 million from fiscal year 1989 funding levels. The largest decrease in funding is the approximately 35 percent in occupational safety and health funding.

Although the Centers for Disease Control has a vital role in the response to and prevention of disease and injury in this country, a recent report issued by the prestigious Institute of Medicine has found that the public health systems in this country is in disarray.

We spend over $7 billion a year, exclusive of AIDS research, in the field of health research. Yet, the budget request for prevention and response to disease and injury is only about 12 percent of the amount we spend on research.

PREPARED STATEMENT

Dr. Dowdle, welcome to the subcommittee. If you would please identify those individuals with you and then summarize your remarks, I'd appreciate it. Your statement will be made a part of the record in its entirety.

[The statement follows:]

STATEMENT OF WALTER R. DOWDLE

Mr. Chairman and members of the committee, it is a pleasure to be here to support the fiscal year 1990 budget request for the Centers for Disease Control.

The recent publication of the Institute of Medicine (IOM): The Future of Public Health reexamines the mission of public health and the roles of the different levels of government and makes specific recommendations for strengthening the public health system. The findings of this report underscore the importance of CDC's leadership role in capacity building at State and local levels through a "people-to-people" approach to public health.

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CDC takes quite seriously its mission to provide leadership in specific activities "To assure the conditions" necessary for all Americans to be healthy. This means undertaking activities to prevent illness, injury, disability, and death, and to improve the health and quality of life of all Americans.

This also means assessing State and local health agencies to strengthen their own capabilities in management, policy development, and program assessment.

Mr. Chairman, it is impossible to present the 1 year of accomplishments of more than 4,500 dedicated people in a few minutes. Therefore, I am going to share with you some of the promising events that CDC has been involved in during the past year in the prevention of chronic diseases, in the control of injuries and infectious diseases, and within the workplace and the environment.

In the area of prevention and health promotion, two recent organizational changes have vastly strengthened CDC's ability to develop innovative methods to prevent chronic disease problems and promote healthy lifestyles.

First, we have brought together all those programs directed at preventing chronic disease to form a new Center for Chronic Disease Prevention and Health Promotion. Second, we have welcomed the National Center for Health Statistics into the CDC family. These two organizations have already demonstrated creative approaches to address the leading chronic diseases—heart disease, cancer, including breast and cervical cancer, diabetes, and high blood pressure.

The prevention of injuries is a relatively new interest in the public health community, and we have been able to initiate programs in both research and injury prevention.

As seen in this chart (chart No. 1), data from NCHS show the death rates from natural causes in Americans aged 15 to 19 are not significantly different from those of other industrialized countries, but rate of deaths from violence and unintentional injuries are much higher.

The results of our research have identified opportunities for averting significant potential years of life lost, disability, and unnecessary economic burden. For example, after conducting 13 investigations of teen suicide clusters, CDC combined epidemiologic research and community collaboration methods to develop and publish recommendations for a community plan to prevent teen suicides.

Our new Viral/Rickettsial Disease Laboratory, which was dedicated last October, allows us to continue to make progress in the control of agents that cause such infectious diseases as Lassa Fever, Viral Encephalitis, Acquired Immunodeficiency Syndrome, Rabies, Rocky Mountain Spotted Fever, and new and unknown diseases. This is one of the few facilities of its kind in the world, and it represents the best in modern containment design and laboratory construction.

Significant technological advances have enhanced our opportunities to address environmental and occupational hazards. The success of the Agent Orange study, designed to determine whether Vietnam veterans developed health problems related to exposure to dioxin, CDC's environmental health laboratory developed a test that can measure dioxin in blood in parts per quadrillion. The findings of the study showed no significant difference in blood levels of dioxin between men who served in Vietnam and similar veterans who did not.

CDC is currently looking into new opportunities to prevent injury and disease in rural populations. Agricultural workers have the second highest occupational fatality rate, after mine workers.

Promising developments in science, technology, and disease prevention—along with a dedicated professional workforce—cause us to approach the challenges of the 1990's with anticipation and genuine excitement. We believe that positive changes in the health of all Americans can be achieved during the years ahead.

The administration has indicated that President Reagan's budget for programs within the residual freeze category, such as the balance of CDC activities, is a starting point for the congressional budget process. The President's fiscal year 1990 budget requests $573,558,000 for prevention, control, research, and training activities. This amount does not include the $474,022,000 proposed for HIV research and prevention, which is allocated to CDC from the consolidated budget request of the Office of the Assistant Secretary for Health.

Mr. Chairman, while much remains to be done, CDC is making progress in combating the major killers of our time and in promoting health.

Thank you for the opportunity to appear before this committee. I will be pleased to answer any questions that you may have.

INTRODUCTION OF ASSOCIATES

Dr. DOWDLE. Thank you, sir. On my far left is Dr. Alan Hinman, who is the Director of the Center for Prevention Services. Sitting next to me is Dr. Donald Millar who is the Director of the National Institutes for Occupational Safety and Health, and sitting to my right is Mr. Claude Pickelsimer, who is the Director of our Financial Management Office, and, of course, Mr. Williams, whom you have seen in the previous presentation.

I would like to thank you very much. I will, of course, submit my statement for the record. I would just like to make several comments.

First, we are very proud of the progress that we have made at CDC in the past year under Dr. Mason's leadership, and we are also proud that Dr. Mason has been nominated as the new Assistant Secretary for Health.

Two particular points I would like to highlight are that we have created a new center for chronic diseases at CDC to better position ourselves to take advantage of prevention opportunities in chronic diseases, and second, that we have positioned ourselves, during the year and will continue to do so, in response to the Institute of Medicine's report on the problems within the public health structure. I think we have made great progress in that area.

I guess, as you can probably tell, we haven't made any progress with the common cold. I think I may have a little problem during this discussion, and I'm sure you will appreciate that.

Senator HARKIN. I've got a terrible one.

Dr. DOWDLE. Thank you, sir.

Senator HARKIN. Did you have anything more you wanted to say?

Dr. DOWDLE. No; that's it. Thank you.

Senator HARKIN. I would recognize first Senator Bumpers. Did you want to ask questions right now?

Senator BUMPERS. No.

Senator HARKIN. Do you have any questions?

VITAL STATISTICS COOPERATIVE PROGRAM

Senator STEVENS. I do have some questions if you don't. I have just three.

I am pleased to be here with you, and I do have a great deal of respect for what your center does. We have had to deal with it on several instances with regard to problems affecting my State and the west in general. I do appreciate the cooperation that you have given to members of the Senate in responding to very important questions from our constituents.

However, it is my understanding now that the vital statistics cooperative program that was switched last year to the National Centers for Disease Control budget is now being considered at a lower priority. What we have heard is that the director of the National Center for Health Statistics plans to reallocate funding away from that cooperative program despite the fact that we increased funds last year in this committee. Is that right?

Dr. DOWDLE. Well, the costs of the surveys have gone up all over. There is a $5 million increase in the fiscal year 1990 request for

the National Center for Health Statistics, but that is from evaluation funds within the Public Health Service.

It is true that we have notified the States that the collection of marriage and divorce vital statistics will not be able to be conducted in the same manner as previously.

Senator STEVENS. Well, why is that we increased the funding? We believe it is a very important function.

Take a small State like mine that is really doing some in-depth studies right now concerning our native population. You may know we have staggering suicide rates and staggering rates of infant mortality. We have another program working on alcohol and drug-related death, and another program working on the whole problem of accidental injury and trying to segregate those out with regard to the various causes that are involved.

Now we have been told by the Department of Health and Social Services in the State of Alaska and our Department of Vital Statistics and also the Public Health Service people up there in Alaska that this money is going to be either reduced or eliminated. Which is it?

Dr. DOWDLE. The program for collecting marriage and divorce statistics will be eliminated. That is the plan.

Senator STEVENS. Is that the only thing you're dealing with is marriage and divorce?

Dr. DOWDLE. That area would be the primary recipient of the cutback.

By the way, that information will still be available, but it will not be available in the same manner or in the same detail as has been provided in the past from the National Center for Health Statistics.

Senator STEVENS. I have been told that Alaska has been notified that the funding for the monitoring of suicide and infant mortality rates and also these alcohol and drug-related deaths are going to be reduced. Is that right or wrong?

Dr. DOWDLE. Dr. Feinleib is here. With your permission, sir, Dr. Feinleib, can the Director of the National Center for Health Statistics comment directly.

Senator STEVENS. Yes, sir; good morning.

Dr. FEINLEIB. Mr. Stevens, thank you for the questions.

Our budget for the vital statistics program in 1989 was $16.9 million. The request for 1990 is $17.1 million, an increase of over $200,000. But because of the activities that have to take place in 1990, this is not enough to cover all of the high priority areas.

In particular in 1990, we are introducing new standard certificates, and we have to go through a large process converting over from the data that have been used in the 1980's to the new data that will be used in the 1990's. This requires a lot of training costs, and we're giving the highest priority to the birth and death registration activities.

Marriage and divorce data are obtainable from some alternative surveys that we do and also in summary form from each of the States. So, we will have some data available on marriage and divorce, but not in the great detail that we have had for the past 30 years.

Senator STEVENS. Well, I'm not really interested in marriage and divorce statistics in terms of this. I can understand that they may be another problem.

But in the first place the VSCP was switched to your budget last year. Is that right? It just came into the budget last year.

Dr. FEINLEIB. It has always been part of the National Center for Health Statistics. The National Center for Health Statistics was made part of CDC last year.

Senator STEVENS. All right.

Well, are you or are you not going to reduce the support you are giving to States to monitor things like suicide, infant mortality, drug-related deaths, and deaths from violent injuries and the causes thereof?

Dr. FEINLEIB. All of those programs will be maintained.

Senator STEVENS. They will all be maintained?

Dr. FEINLEIB. From the vital statistics point of view, that is correct. The main reduction in the vital statistics area will be in the marriage and divorce data.

Senator STEVENS. Did you take pains to notify the States of that, that the reductions were only at divorce and marriage?

Dr. FEINLEIB. As a matter of fact, I will be presenting at the meetings of the State vital statistics people in 2 weeks, exactly that message. Yes, sir.

Dr. DOWDLE. For the record, sir, I would like to again restate that NCHS has a $5 million increase in fiscal year 1990. In fact, it is the only CDC organization that received an increase this year, and the additional moneys were requested largely to take care of the increasing expense for surveys.

Senator STEVENS. My chief concern—and I don't want to be too redundant—is that we not get in the position where we are getting statistics in the State of Alaska that don't correspond with national statistics being gathered elsewhere so we can, in fact, compare these rates and make a case, if there is one to be made, that we have a crisis in these remote areas of my State. We think there are. As a matter of fact, a newspaper that went out and did reporting on this in depth has just received a Pulitzer prize for that total coverage. I don't know if you paid any attention to it, but I did considerably.

Now, it demonstrates—the reporting that was done—it was very good reporting—indicates that the statistics are getting, as far as we are concerned, as far as the Alaska native population is concerned, totally out of phase with the total national statistics. My State people tell me that if you make the changes you intend to make, that we will have to gather our own, but you won't be gathering the national ones either now. Now, is that right?

Are you going to make any changes in the statistics that relate to infant mortality, death from alcohol or drug abuse, violent injury as far as death and the causes thereof? Are you making any changes in that at all?

Dr. FEINLEIB. I think there is one area that there may be some confusion about. The area that you describe as part of the vital statistics system will be maintained.

There was a new program introduced about 2 years ago that we called the linked files, which linked the infant deaths to the birth

records. This was funded for a 4-year period out of a variety of funding. And we will continue that for what we call the birth cohorts in 1983 through 1986, which will carry it through 1990. But we do not yet have the funds to maintain that beyond the 1986 cohort.

Senator STEVENS. Is there money in this budget for it?

Dr. FEINLEIB. No; there is not, sir.

Senator STEVENS. How much was that?

Dr. FEINLEIB. That is $300,000 to $400,000, sir.

Senator STEVENS. Will you give us a note on that?

[CLERK'S NOTE.—Dr. Feinleib provided the committee with the figure of $300,000 for funding of State and related costs.]

How much is in the current year, 1988?

Dr. FEINLEIB. About that level for the program, sir.

INJURY PREVENTION

Senator STEVENS. With regard to injury prevention, it is my understanding that injuries really relate to the childhood mortality figures and that the adult rate is not much better. But do you place a focus on injury prevention in terms of your activities?

Dr. DOWDLE. Yes, sir; we do, both in terms of research on injury prevention and State activities. State prevention projects, for example, are also focused on injury prevention. We feel that many of the 150,000 deaths that are caused by injury each year for all ages can be prevented, and it is an area in which a major effort is long overdue.

Senator STEVENS. You have a Center for Disease Control?

Dr. DOWDLE. Yes, sir.

Senator STEVENS. And it has a very great reputation.

Why don't you have some sort of center that deals primarily with injuries, particularly with regard to those that relate to infant mortality?

Dr. DOWDLE. We would like very much to do that, just as we have created a center this year for chronic diseases. As soon as we get to the point where we have the critical mass to create a center, we would like very much to do that.

Senator STEVENS. Have you ever costed out such a center for injury control or prevention?

Dr. DOWDLE. Yes, sir; I think in order to start, we would need approximately 150 FTE's, of which we now have about a third or fewer, and then something in the neighborhood of about $50 million to start such a center.

Senator STEVENS. Would you be willing to give to the committee a—let me back up. Did you ever ask for money from OMB to do that?

Dr. DOWDLE. Not for that large an amount, no, sir.

Senator STEVENS. I understand that, but I am particularly interested in some sort of focus on these injuries that tie into these increasing childhood mortality figures throughout the country. And I wonder if you have ever asked for money to establish an institute or a separate center for this injury prevention.

Dr. DOWDLE. Just to clarify that, we have not asked to start an institute or a new center. That has not been requested of OMB.

Our request this past year was $18 million additional, which would make about $38 million.

Senator STEVENS. And what did you get?

Dr. DOWDLE. We would be getting $10 million for in-house and cooperative agreements and $10 million that is slated for transfer to the prevention block grants.

Senator STEVENS. Well, I would be very interested if you would submit to the Appropriations Committee an outline of the type of—maybe I'm using the wrong words—the type of organization you would create within your overall control within CDC to address the problems of injury control and to give us some indication of how that money would be allocated for research, injury prevention research centers or projects or training, and some idea of the scope of what you might envision if we could be successful in finding that money.

Dr. DOWDLE. Considering the size of the problem, sir, we think the center would be appropriate. Yes, sir; we'll do that.

[The information follows:]

CENTER FOR INJURY CONTROL

If resources were available within the budget and deficit reduction targets, a minimum of 150 FTEs and $50 million would be needed to establish a center for injury control.

Funds would be used to support grants for research projects, injury prevention research centers, and State and local agency programs, including public health surveillance for injuries and injury prevention projects. CDC intramural staff and its program would be expanded to establish technical and programmatic expertise in acute care, biomechanics, and rehabilitation. Program expertise and activities would be strengthened to focus on injury problems among high risk populations, for example, children, elderly, rural, minority, and poor. The program also would target efforts to evaluate strategies to reduce violence, including homicide, suicide, and assault.

Funding at this level to establish an injury control center would support approximately 75 extramural research projects, 14 injury prevention research centers, 50 State and local programs for capacity building and demonstration, and increased support for intramural research and technical assistance and training. Approximately 80 percent of the funds would support extramural research and technical assistance and training.

INFANT MORTALITY

Senator STEVENS. It is an alarming problem, Mr. Chairman. It is increasing. I thought our infant mortality rates were going down and they are as far as delivery and childbirth. They are going up in terms of injury-related mortality right now.

Dr. DOWDLE. Yes; that's correct.

Senator STEVENS. I think it is something we ought to address. It doesn't sound like a lot of money.

How many people did you say you would need?

Dr. DOWDLE. We would need a minimum of about 150 FTE's to get a center started. That is a minimum requirement in order to meet the criteria for a center.

CDC FTE'S

Senator STEVENS. How many do you have in the Centers for Disease Control now?

Dr. DOWDLE. Well, our total number of FTE's is about 4,500 for fiscal year 1989. This level is expected to be further augmented by about another 640 FTE's exempt from employment ceilings, which are primarily public health advisers working with the States. This would bring the total CDC staffing level to almost 5,140 FTE for fiscal year 1989.

Senator STEVENS. That's not a very big operation.

I appreciate your cooperation. I thank you very much for your courtesy.

IMMUNIZATION PROGRAM

Senator HARKIN. Senator Bumpers?

Senator BUMPERS. Mr. Chairman, I want to direct a few questions to Dr. Hinman on immunization funding. I am concerned, first of all, about the State operation funding being cut, Dr. Hinman. I assume that CDC has been told to hold the line on immunization funding. First of all, we are cutting State operations from $18 million to $16.9 million, a little over a $1 million cut.

The States have been picking up an increasing share of immunization costs, and that is laudable. But I am concerned about their ability to handle measles outbreaks. They have been kind of left on their own to do that. It seems to me that this is a rather impropitious time to be cutting back on State operation funding.

Dr. HINMAN. Senator, the State operations funds support some of the activities relating to measles outbreak control. Of course, one of the major costs is the vaccine itself. Our priority in budget development within the guidelines has been to try to maintain a supply of vaccine. The budget request for fiscal year 1990 will provide the same number of doses of vaccine that will be purchased in fiscal year 1989. But, as you point out, it does so by shifting about $1 million from support of State operations to purchase of vaccine.

Senator BUMPERS. When I see figures here that say totals for grants are the same in 1990 as they are in 1989, I figure you have had a communication from OMB telling you that you are going to have to live with the same money you had in 1989.

Dr. HINMAN. Senator, I don't believe the budget deficit has gotten any smaller this year.

Senator BUMPERS. You don't believe what?

Dr. HINMAN. That the budget deficit has been getting smaller, and we have, in fact, been trying to work within the confines of budget restrictions.

Senator BUMPERS. Well, if there is a place in the whole U.S. budget where you ought not to concern yourself with the budget deficit, it's in the immunization program. The immunization program in my opinion is still the most cost-effective program in the United States.

I really think Ronald Reagan and my colleagues in the Senate got in more trouble in 1981 trying to cut immunization funding than cutting other programs. They could hardly wait to go back and cover their rears over their vote to cut immunization because the people of this country know that that program is absolutely vital, not just to children but to all of us. I'll get to hepatitis B in just a moment because I am really concerned about that.

First, have the costs of vaccines increased in the past 12 months?

VACCINE INJURY COMPENSATION

Dr. HINMAN. The cost of vaccines in the last 12 months has increased slightly. The major increase that we had recently was the imposition of the excise tax on vaccines to fund the trust fund for vaccine injury compensation.

Senator BUMPERS. Incidentally, that fund is building at a faster rate than we projected.

Dr. HINMAN. I believe at the end of last year it had something in excess of $100 million.

Senator BUMPERS. That's right. Now, you understand that claims have just begun to come in.

Dr. HINMAN. There have actually been received to date about 115 claims.

Senator BUMPERS. But none of them have been adjudicated yet, have they?

Dr. HINMAN. I think there has been one final decision, but most of them are still in process. That's correct.

These claims are all for injuries occurring before October 1, 1988.

Senator BUMPERS. The claims that are filed now are before October 1988 is it or 1987?

Dr. HINMAN. Eighty-eight.

Senator BUMPERS. Before October 1988.

Dr. HINMAN. That's correct.

Senator BUMPERS. OK.

Dr. HINMAN. What are called the prospective claims, which are the claims intended to be paid out under the trust fund, have not yet occurred because they have to have had 6 months worth of injury before a claim is filed. And so, the first possible date for filing a claim for a new injury would have been on April 1 of this year.

Senator BUMPERS. Dr. Hinman, these measle outbreaks are caused from a number of things. The vaccine prior to 1980 was not as effective as we thought.

But Dr. Howard Hiatt of Harvard University, whom you probably know, stays in close contact with the princess of vaccinations, Betty Bumpers. Dr. Hiatt says that 60 percent of the inner city children in this country are not immunized against polio. Do you think that is an accurate figure?

Dr. HINMAN. I think that is probably something of an overestimate. We do know that immunization levels in our inner city disadvantage children are much lower than they are in school age children and much lower than they are in young, preschool age children in more affluent areas. We have some estimates in surveys of immunization levels on the order of 50 to 55 percent in inner city disadvantaged children.

Senator BUMPERS. Now, we also have that same problem of measles immunizations levels among inner city children, do we not?

Dr. HINMAN. Yes, sir.

OUTREACH PROGRAM

Senator BUMPERS. You apparently have some outreach demonstration projects that you want money for, is that correct, or that you plan to do with money you have, one or the other?

Dr. HINMAN. That is correct.

Senator BUMPERS. Now, describe that outreach program and how many of them are there going to be?

Dr. HINMAN. Depending on the availability of funds, we are currently planning two to four projects which will look at more effective ways of measuring inner-city immunization levels and trying to get young infants in the inner-city immunized. There are a variety of reasons why these children are not immunized, ranging from difficulties in access to competing priorities on the part of the parents, as well as the problem that children are being seen primarily when they are ill and are often not given vaccines because they have another illness. So, our hope is to try to define the major factors that are responsible for the low immunization levels and design approaches to improve them.

MEASLES OUTBREAKS

Senator BUMPERS. That doesn't seem to me like a very dramatic program to address what I consider a fairly dramatic problem, the immunization of these preschoolers in the inner cities. It is fine to make people bring you a certificate when the child enters kindergarten or first grade, and that was a real step in the right direction. But the preschooler problem is a big one in the inner city.

I just don't believe that two programs are really adequate to reach a significant number of the immunized. So, we may wind up, unless you can give me a good reason not to, giving you more money than you want for a much more extensive outreach program for those inner-city children.

These measle outbreaks are very expensive when they occur. We are going to have more measles this year than we have had since when?

Dr. HINMAN. Probably more measles this year than since 1980.

Senator BUMPERS. Well, that is a real travesty. These college campus outbreaks are usually because of the vaccine not being as effective as we thought. Isn't that true?

Dr. HINMAN. They occur for a combination of reasons, Senator. Some of it relates to the fact that before 1979 the vaccine was not as stable in the presence of heat as it is now. Some of it relates to some students not having received vaccine at all. Some of it relates to the fact that measles is so highly infectious that even in the presence of 95 to 96 percent immunization levels, we have seen transmission of measles. Although the vaccine itself is 95 to 98 percent effective, there will be a small proportion who have received vaccine——

Senator BUMPERS. Who will become infected.

Dr. HINMAN [continuing]. Who will become infected if exposed.

It is for that reason that our Advisory Committee on Immunization Practices has recently recommended a much more aggressive approach to revaccination in the face of outbreaks of measles both in the school setting and in the college setting. They have recom-

mended revaccination of everyone who received vaccine before 1980. This has posed an important additional tool, but it also has posed an important additional resource drain for States, as you point out.

Senator BUMPERS. It has been very tough on three or four States trying to deal with that.

Dr. HINMAN. Yes, sir.

Senator BUMPERS. My State is not one, but I have an interest in the other States.

Dr. HINMAN. North Carolina is a State which took a very aggressive approach in outbreak control and, in essence, spent nearly its entire immunization grant for the year in the first 3 months of this year.

VACCINE STOCKPILE

Senator BUMPERS. Dr. Hinman, you had $4 million this year for vaccine stockpile, and you are not asking for anything in 1990. Explain that.

Dr. HINMAN. The vaccine stockpile at the end of this year will be about 80 percent complete for our target of having a 6-month supply of childhood vaccine.

We are hopeful that the Vaccine Injury Compensation Act will reduce the liability pressures on vaccine manufacturers, and that in turn will make the climate more attractive so there will be, first, a price stabilization, and, second, perhaps entry into the marketplace of more manufacturers.

Senator BUMPERS. But that is only a hope.

Dr. HINMAN. That is correct.

Senator BUMPERS. What if that doesn't prove to be the case and you have outbreaks?

Dr. HINMAN. The stockpile has to date been very useful to us.

Senator BUMPERS. How big a stockpile do you have under normal usage? If you were just going to use up your stockpile for normal immunization usage right now, how long would it last?

Dr. HINMAN. Of the vaccine that we have ordered for the stockpile, not all of which has been delivered, we have approximately a 20-week supply of childhood vaccines.

Senator BUMPERS. Dr. Hinman, I am not going to try to put more money in the budget for that stockpile if you say you don't need it, but I want you to know your neck is out that far if you run short. I would rather see you throw vaccine away than to not have an adequate stockpile and need it. But as I say, I am going to defer to your professional judgment on that, and I am not going to try to get this subcommittee to put more money in there.

Which brings me now to my final point.

Senator STEVENS. Haven't we put that back in every year?

Senator BUMPERS. Well, we have never had a request for zero funding for it to my knowledge.

Dr. HINMAN. I believe you have.

Senator BUMPERS. Have we?

Dr. HINMAN. Yes, sir.

Senator BUMPERS. And we have always restored it?

Dr. HINMAN. Yes, sir.

Senator BUMPERS. Well, why don't you send me a personal and confidential letter and tell me how you really feel about it then? [Laughter.]

Dr. HINMAN. Senator, as a program manager, I would feel more comfortable with a larger stockpile than I have now.

Senator BUMPERS. That is fine. I appreciate hearing that.

Now, Dr. Hinman, despite immunization of more than 1.4 million persons——

Senator STEVENS. Senator Bumpers, would you yield for just one moment?

Senator BUMPERS. Certainly.

DEMONSTRATION PROJECTS

Senator STEVENS. One point here, and that is these demonstration projects. Could we go into that and see what the funding level would be for the size of project programs——

Senator BUMPERS. Certainly. Dr. Hinman, you said that you wanted two to four projects, two to four pilot projects, in the inner city.

Dr. HINMAN. That is what I believe we'll be able to support this year. However, these projects will vary in cost depending on the size and locations of the demonstrations.

Senator BUMPERS. What do you anticipate the cost of those would be?

Dr. HINMAN. At the present, we estimate $1 to $2 million for the two projects.

Senator BUMPERS. So, that would be $500,000 to $1 million per project?

Dr. HINMAN. Yes, sir.

Senator BUMPERS. Well, there again, we need your professional judgment on this. Is that adequate, or in a perfect world, would you like to do more demonstration projects?

Dr. HINMAN. Senator, if you are asking my personal opinion, I would very much like to be able to do more projects.

Senator STEVENS. If you don't mind my butting in, how big a program can you handle? I think this is an alarming statistic.

Dr. HINMAN. From a practical point of view, I think probably it would be difficult to handle more than five or six projects at a time.

Senator STEVENS. A $10 million program?

Senator BUMPERS. That would be roughly a $5 million program if you are assuming each one would cost roughly $1 million.

Dr. HINMAN. Roughly.

Senator BUMPERS. Senator, those projects are very expensive because you have to knock on their doors. You have to lead them to the clinics. And it is a very expensive program.

Senator STEVENS. I understand what you are saying. It is not one of the problems of my State, having that kind of problem in the inner city. But I do think that, without question, that it is a cost preventive operation and that as a father, I can't believe we have those children who are going to enter into federally supported kindergarten operations soon that are not immunized. I think it is bad.

Senator BUMPERS. Senator, believe it. I tell you I get these immunization lectures at my house every evening. Betty is still on the advisory committee and comes back with all these alarming stories every time she goes to Atlanta for a meeting about this. I was really shocked to read Dr. Hyatt's letter to her the other day on this to find that 60 percent of the inner city children are not immunized against polio. The incidence of children not immunized against measles in the inner city is going up dramatically.

Senator STEVENS. Why don't you ask him to give you an outline for the Betty Bumpers immunization program for the country and see what it would cost? You have a lot of friends over here who would be glad to help you.

Senator BUMPERS. Well, I'll be frank with you, Senator. I think the main problem right now is in the inner city. Is that not correct, Dr. Hinman?

Dr. HINMAN. In terms of achieving high levels of immunizations, our major problem, I think, in children is inner city preschoolers. Even in the inner city, by the time children enter kindergarten, Senator, they are very well immunized because of the immunization requirements. At the time of first entry to kindergarten or school, more than 95 percent of children are immunized, and that is nationwide. The problem is getting children immunized——

INFANT MORTALITY

Senator STEVENS. What are the infant mortality rates in that period due to lack of immunization? You are saying by the time they reach the age of 4 or 5, they are going to be immunized.

Dr. HINMAN. That's correct.

Senator STEVENS. What are those rates? Are they as bad as I think they are?

Dr. HINMAN. Well, in terms of mortality from vaccine preventable diseases, we fortunately have very few deaths due to the childhood vaccine preventable diseases. For example, last year I think we had six deaths due to measles in this country. We had no cases of polio in this country.

Senator BUMPERS. Did you have any whooping cough cases last year?

Dr. HINMAN. Yes, sir.

Senator BUMPERS. Any deaths?

Dr. HINMAN. I don't have the final figures, but we typically have between 5 and 20 deaths a year ascribed to whooping cough. This compares to 9,000 deaths in the 1920's in a year due to whooping cough.

Senator BUMPERS. I know what the risks of vaccines are, but that is not the point. I mean, any pediatrician will tell a mother, if she asks, to have her children immunized. But then they come with those stories and show those profound reactions which do, indeed, occur.

Dr. HINMAN. It is very difficult to portray the benefits graphically.

Senator BUMPERS. Yes; it is. And they are not in the business of showing benefits.

HEPATITIS B VACCINE

Doctor, let me just close by asking you about the hepatitis B vaccine. I am really concerned about the figures that my staff has given me on that.

But it seems to me that the solution to that is long-range because a lot of these mothers are carriers, and so far as I know, there is no treatment now to eliminate the carrier. Is that correct?

Dr. HINMAN. That's correct.

Senator BUMPERS. Now, I was about to read, a moment ago, that we have had this vaccine since 1982 to prevent hepatitis B—the hepatitis B vaccine. And here is a quote: "Despite immunization of more than 1.4 million persons, disease incidence has increased 50 percent since 1982." So, we are really going backwards fast, aren't we?

Dr. HINMAN. We certainly have not had the implementation of hepatitis B vaccination that was envisioned. The 1.4 million persons who have received vaccine have been primarily health care workers and other individuals at risk of exposure industrially.

A recent recommendation from our Advisory Committee on Immunization Practices, of which your wife is a member, is that all pregnant women should be screened for the presence of hepatitis B virus, and if they are found to be carriers of the virus, then their newborn infants should receive vaccination. At present, our best estimate is that in the private sector, a substantial proportion of women, perhaps 50 percent of pregnant women, are in fact being screened. We do not have comparable coverage in the public sector.

Senator BUMPERS. Dr. Hinman, let me read this for the benefit of the committee and the record. "Of the 3.8 million women who deliver each year, about 16,500 will be HBV positive at delivery, resulting in 16,500 infants who become chronic HBV carriers."

Now, as I pointed out a moment ago, those female infants some day are going to be having babies, and they in turn have a good chance of infecting their fetus, isn't that correct?

Dr. HINMAN. That's correct.

Senator BUMPERS. Because there is no way to remove that virus from that infected child.

Dr. HINMAN. No, sir.

Senator BUMPERS. If prenatal screening of pregnant women is conducted, those newborns who are found to be positive can be treated with hepatitis B immune globulin and hepatitis B vaccine, a combination that is 85 to 95 percent effective in preventing the chronic carrier state in the newborn. Although there are only 265,000 women delivering each year who are considered high risk, there are major problems with screening only this group and a universal screening is more realistic.

Now, I am really troubled, Dr. Hinman. Again, you have not requested one dime for a public program to combat hepatitis B. Does that trouble you?

Dr. HINMAN. Does it trouble me personally? Yes, sir.

Senator BUMPERS. Well, does it trouble you professionally?

Dr. HINMAN. Yes, sir.

Senator BUMPERS. As a matter of protecting the public health of this country, wouldn't you agree with me that this problem needs to be addressed?

Dr. HINMAN. Yes, sir; we have made estimates as to what would be involved in trying to address that.

Senator BUMPERS. If this subcommittee asked you to present to us a program—we not only have a right, but I can tell you we are getting ready to do that. We are going to ask you to submit to us a program, maybe two or three different ones, the optimum program and one that you think would be effective. But we cannot address this problem intelligently without your help.

When you think about 16,500 babies being born a year that are hepatitis carriers and they are going to be carriers all of their life, and a lot of them are going to be female who, in turn, transmit it to their children. To sit here and do nothing about that is just not acceptable to me.

I do care about the budget deficits, of course. But I tell you when I think about programs like this scrounging around for $2 million or $3 million and us out here debating about MX, midgetman, and SDI, I get red in the face, as you notice.

Senator HARKIN. At the risk, Senator Bumpers, of making you more red in the face, you ought to get a copy of this book, The Future of Public Health, recently put out by the Institute of Medicine—I know you are all aware of it—and read pages 19 through 35 on the disarray of public health in the United States and what has happened over the last several years.

Senator BUMPERS. The other day I was down in Brazil. We were down there to study the greenhouse effect and, of course, the Brazilians just get spitting mad when the gringos come down there and tell them what to do with the tropical rain forest. We weren't trying to tell them. We just wanted to see it and make the point.

But we went into this Chamber of Deputies, a committee room. There were about 50 deputies comparable to our House of Representatives, the Chamber of Deputies. Of course, I don't speak Portuguese. But when these deputies spoke, they sounded so volatile and they were pounding the table. The translator would come across saying we welcome all these Senators from America. We are most honored to have you in our midst. [Laughter.]

Sometimes Senators sound that way, but we do have an immense respect for you professionally.

Without this committee formally requesting this report from you, let this just be the request for information on a hepatitis B screening and immunization program.

Dr. HINMAN. Yes, sir.

Senator BUMPERS. Thank you.

HEALTH HAZARDS IN SCHOOLS

Senator HARKIN. We are honored to have the distinguished chairman of the full Appropriations Committee, Senator Byrd.

Senator BYRD. Thank you, Mr. Chairman.

Dr. Millar, according to newspaper reports, students and staff at the Andrew Jackson Junior High School in Cross Lanes, Kanawha County, WV, have been experiencing a number of unexplained ill-

nesses: Tingling; numbness; pain in their limbs, shoulders, and back; and blurred vision. Several have been diagnosed as having neurological problems.

The county health department could not find any problem at the school. At the request of Senator Rockefeller and Representative Wise and I, the National Institute for Occupational Safety and Health undertook a health hazard investigation.

NIOSH was at the school I believe on 2 successive days. I understand NIOSH found a drum of hydrochloric acid in the chemistry lab, which was removed, and took air samples, and it has not made any official report. So, there may be considerable conjecture at this point.

I first want to thank you for the quick response.

Can you tell me what has been learned? What is your assessment of the problem there? Do you feel that the classrooms are safe for teachers and students? When do you expect the report to be made available?

Dr. MILLAR. Well, as the Senator said, what I can say about conclusions is a little preliminary because none of the laboratory studies have yet been finished, but I think the situation is fairly clear.

We sent a physician and an industrial hygienist there to conduct this investigation as part of our ongoing health hazard evaluation program which, in fact, gets us into about 500 work places a year responding to just these kind of cries for help.

I think the situation here was actually very well handled.

They identified some chlordane exposures. Chlordane is a pesticide which is used to protect the building from bugs. It does, in fact, have the capability of causing some of the symptoms that were observed here.

So, our laboratory investigation of this situation will focus on whether or not the environmental samples show the presence of chlordane in sufficient quantity that it could have produced these symptoms.

But I think between the chlordane and the hydrochloric acid which was found in an open container, there probably was certainly a problem with indoor air quality in that particular school.

We were pleased to be able to respond. We think this is an important development.

Senator BYRD. What is your assessment, if you can make one at this point, preliminary though it may be, of the danger to teachers and students in the classrooms there?

Dr. MILLAR. Well, the hydrochloric acid has been removed, so that source of the problem is gone. The two classrooms in which we found some evidence that chlordane might have been at increased levels on the basis of circumstantial evidence have been closed. So, I think probably the problem is well-handled at this point. Once we get the samples analyzed, then I think we will be in much better shape to advise when and how to reopen the two classrooms.

Senator BYRD. You will be submitting a report.

Dr. MILLAR. Yes, sir; we will. We submit reports after each of these HHE investigations. Sometimes it takes us a little longer than the requesters like to get those reports out, but we will try to do our best in this case.

Senator BYRD. How long do you think it will take to submit the report, and can it be expedited?

Dr. MILLAR. I would guess that we could provide an interim report with the conclusions in 2 weeks. It may be a little longer than that getting a final written report.

Senator BYRD. Will NIOSH be taking any additional air samples at the school?

INDOOR AIR QUALITY

Dr. MILLAR. What we usually do in these cases is to be sure that the officials involved understand the nature of indoor air quality problems. Basically, most of these problems involve ventilation aspects, and I'm told that in this case there were some deficiencies found in the ventilation system. That is by no means uncommon. We find that virtually every time we look.

I am sure that advice has already been given about dealing with that. I think we will no doubt advise the people there in West Virginia to keep us posted, and if there is any continuing problem, then we will be looking back into it. That is a standard approach in dealing with indoor air quality problems.

Senator BYRD. Will NIOSH be taking air samples as a follow-up to the work that has already been done?

Dr. MILLAR. I am not aware that we will be doing any more sampling unless the results of what we have done so far would indicate some reason to follow that up.

Senator BYRD. How will you know if the results are what we want them to be unless you follow it up with some air sampling?

Dr. MILLAR. Well, I think if we find clear-cut elevations of agents in the samples we have already taken, we would obviously want to come back after a period of time to be sure that those levels have disappeared.

Senator BYRD. Will you supply me with a copy of the report when it is completed?

Dr. MILLAR. We certainly will.

Senator BYRD. I want to thank you for the attention that has been given. If you can expedite the report, that would be very good I think. It would indicate as to whether or not there need to be further air samples as well. Thank you very much.

Thank you, Mr. Chairman.

AGRICULTURE AND RURAL HEALTH SAFETY

Senator HARKIN. Thank you, Mr. Chairman.

Dr. Dowdle, I just want to cover the area of agricultural and rural health and safety.

I'm sure you know that agriculture has the second highest occupational fatality rate in the Nation. About 90,000 disabling injuries occur each year, and 300 children are killed each year in farming accidents. Studies done by the Centers for Disease Control have found a disproportionate share of injuries and disease associated with numerous chemical, biological, and physical hazards. I think it is apparent that rural health and safety is a huge problem, a problem that we have not as yet really addressed.

It would appear to me that the Centers for Disease Control is in a unique position as the only Federal agency engaged in activities covering all injury and disease areas to lead a comprehensive national effort to prevent injury and disease in agriculture.

Dr. Dowdle, I want to thank you for the package of 25 initiatives you pulled together at my request. We received this on March 28. To fund all of these rural health and safety initiatives in fiscal year 1990 would cost about $55 million and would include intervention, research, and data collection efforts.

Now, I am not sure we can fund all these proposals in fiscal year 1990. Could you, either now or later, supply to me a list of what you think might be the highest priority items that we might want to look at in fiscal year 1990?

Dr. DOWDLE. In the interest of time, we could provide you those priorities. The way we would like to approach this problem is the way we usually do, and that is to give priorities to those programs that define the problem so that we can then identify opportunities for intervention. We would combine data collection activities with intervention projects that we can do now with the information we have available. The priorities would be based on those criteria. I could give them to you now, but we could supply them to you later as well.

Senator HARKIN. I think that would be better. Why don't you do that for me please.

[The information follows:]

AGRICULTURE AND RURAL HEALTH SAFETY PROJECTS

The 25 projects described were divided among three programmatic areas: Surveillance, research, and intervention. While it is difficult to prioritize the 25 projects, our initial emphasis would be on surveillance and research. Among the surveillance projects, priority would be given to the one-time health and hazard survey and establishing the SENSOR Surveillance System in rural hospitals ($5.5 million). In the research area, priority would be given to establishing the Injury Prevention Center and the Centers for Agricultural Safety and Health ($5 million). The remaining research projects could be initiated but at a combined level of $12.2 million.

While intervention projects may not be as high an initial priority as surveillance and research, we could quickly expand programs that have been proven to be successful and focus these efforts on agriculture workers. A priority in this regard will be expanding State-based injury control programs ($1 million), chronic disease prevention programs ($2 million), prevention of infectious and dental diseases ($1.5 million), and health promotion projects ($2 million).

Also CDC would, in collaboration with the Department of Agriculture and the Association of Schools of Public Health, establish an ASHPS at each of the land-grant universities. These universities could collaborate with the county extension officers and programs to disseminate information and conduct programs to prevent illness and injury among agricultural workers and their families. About $2 million would allow the initial development and funding for this program.

In summary, of the projects listed, $31 million would be higher priority activities in the following areas: Surveillance ($5.5 million), research ($17 million), and intervention programs ($8.5 million). Total FTE requirements at this level would be 76.

FARM-RELATED HEALTH PROBLEMS

Senator HARKIN. I noticed on page 2 of your report you listed three factors contributing to the frequency and severity of health problems among farm-related problems. Do you have that in front of you there?

Dr. DOWDLE. Yes, sir.

Senator HARKIN. Down at the bottom of page 2. Factors contributing to the frequency and severity of health problems. You didn't list there that over the last 20 years the increasing use of chemicals, herbicides, pesticides, et cetera. You didn't list that. I am curious as to why.

Dr. DOWDLE. Yes; in fact, this is an area that NIOSH is also quite interested. Dr. Millar, would you respond?

Dr. MILLAR. I am not sure I can answer the question of why that wasn't listed because it is certainly an accurate statement, as the chairman has said.

Senator HARKIN. Especially when I look at the projects, receiving the most money for cancer, neurotoxic, dermatologic, and other disorders. It indicates that you understand that there is a lot of cancer occurring out there.

Dr. MILLAR. I think that reflects the high cost of doing certain kinds of research related to cancer. If one views the agricultural problem from the point of view of occupational diseases and injuries, clearly the outstanding concerns I would have would be acute injury and then lung disease, occupational lung disease among farmers. Those would be the two that I would see as having the greatest significance.

Yes; there are some evidences of increased cancers of one sort or another. But I think the big compelling problems are the problems of injury and lung disease.

Senator HARKIN. Injury and lung disease.

Dr. MILLAR. Yes.

Senator HARKIN. Certainly injuries. And lung disease too. That is true.

Dr. MILLAR. Things like occupational asthmas, for instance, are very common among farmers.

Senator HARKIN. Well, let me just tell you that several studies over the last years have shown that farmers and farm-related families are more likely to die of leukemia and several other forms of cancer. The causes are still unknown. But farmers in Iowa and other upper midwestern States have been shown to have a higher mortality from lymph, stomach, non-Hodgkin's lymphoma, and prostate cancers. Despite the knowledge that farmers are more likely to develop these cancers, little if anything is being done to promote early identification and treatment in this population.

To what extent has the Centers for Disease Control examined this problem of cancers among farmers? Have you done anything at all?

Dr. DOWDLE. About cancers in the agricultural area?

Senator HARKIN. Yes.

Dr. DOWDLE. That is exactly the point that I was trying to make earlier, that the top priorities would be those that define the problems. That is exactly the type of surveillance that we would undertake. The types of investigations that we would undertake would not only look into the cancer issue, but put it in perspective as well.

Senator HARKIN. That is what you would like to do.

Dr. DOWDLE. Yes; that is right. That would be part of the criteria for determining priority.

Senator HARKIN. Having lived among farmers all my life—I just had a group of farmers in from Iowa this Monday. Well, actually it was a high school group, and they had their chaperons with them.

I don't know how we got off on this topic, but we did. I know. I had to go to chair a hearing, one of these hearings on health. One farmer there said that within 1 square mile of where they live, four teenagers had died of cancer before they graduated from high school. They said that within their township, they had several adults who had also contracted cancer in that one small area.

There is a great concern among farmers and farm families about the chemicals they use, their exposure to chemicals. As I said, we have had studies that have shown these high incidences of cancers.

Knowing farmers, as I do, because they live in a remote area, they may not have a health facility near, perhaps because of their own mental makeup—they are very independent people, stoic, strong—as long as they are feeling well and looking well, they don't think they have to go see a doctor until they really get sick. By that time, it is too late.

I am wondering if you would entertain the idea of having a project that might demonstrate the effectiveness of early screening, early detection, among farmers, especially farmers, to detect any early signs of cancers that might be treated and might be successfully treated if caught at an early time. To my knowledge, there are no programs, at least in Iowa or anywhere that I know of in the upper Midwest, of a nature that would go out through education, through meetings, public dissemination to try to get people into some place, a rural hospital or a rural clinic to do some diagnostic testing just on detecting early signs of cancer.

I am just wondering if any one of these initiatives would permit us to have some kind of a program to take a look at that.

CHRONIC DISEASE

Dr. DOWDLE. Of course, in the creation of the new chronic disease center, we have been interested in promoting prevention for breast cancer and cervical cancer, and our prevention efforts certainly can extend to other cancers.

BREAST CANCER

Senator HARKIN. In breast cancer we have done a lot. Right?

Dr. DOWDLE. Right.

Senator HARKIN. A lot of education, a lot of getting women in early for early detection.

Dr. DOWDLE. Well, we still have a long way to go.

Senator HARKIN. Yes; but it has been a pretty good educational process.

Dr. DOWDLE. That truly is very effective. If a woman comes in early to the clinic and the breast cancer is detected early, you can drop the rate of cancer mortality by 50 percent. It's a very effective program.

But certainly educating people about the benefits of early detection is an interest of CDC, and that is the type of thing that we can do by looking at the agricultural community from different foci within CDC.

Senator HARKIN. I think once you have a couple of projects to demonstrate—we know that early detection of cancer is one of the most effective means of controlling the cancer—that through this kind of early detection and intervention you have been able to save lives and retard the cancer growth, you would get a lot more farmers coming in at an early stage.

There have been a lot of cases and instances like that in Iowa. I talked to people about what we can do to set up that. Then I asked for your program, and you gave me these initiatives. Obviously, $55 million is 10 percent of your entire budget.

I would like to see another list of your priorities. Maybe some of these other ones can be folded together.

Dr. DOWDLE. That's correct.

Dr. MILLAR. Mr. Chairman, I wanted to clarify what I said earlier. I don't mean to demean the findings that have been made by NIOSH in the studies in California and Washington State about increases in cancer of certain types—stomach, kidney, and lung. What I was really trying to do was to portray the entire kaleidoscope of problems faced by farmers and to point out the ones that seemed to us most pressing. I think overarching all of them clearly is the accidental injury.

Senator HARKIN. I have no doubt about that. That is the biggest one. Accidental injuries is the biggest one.

Well, I would just like to follow up on that idea of doing something in that one area. On injuries we also have to do something.

PREVENTIVE HEALTH BLOCK GRANT

I did have a couple more questions. I wanted to ask you about the preventive health block grant. The fiscal year 1990 budget recommends that injury control, prevention centers and diabetes and tuberculosis grants be folded into the preventive health block grant. I understand that this is not a CDC recommendation, but it is an OMB idea.

What is your professional position on this proposed consolidation of these programs?

Dr. DOWDLE. Well, of course, the OMB position regarding the prevention block grants is that these moneys should be provided to the States to allow them the flexibility they need for their programs.

I think one has to consider, though, that a number of these programs require a national focus until they are really at a point where they can be taken over entirely by the States. If these programs are folded into the block grant at such an early stage, then this means that we have to be much more innovative in trying to develop the national focus that we think is needed.

BREAST AND CERVICAL CANCER

Senator HARKIN. Getting back to breast and cervical cancer, each year there are more than 50,000 women who die from breast and cervical cancer. Fifty thousand people dying each year is equivalent to 250 Boeing airline crashes where the planes are full and everyone dies—250 every year.

On page 42 of your budget justification, it states, "the fact that women die of cervical cancer is troublesome since medical technology exists to significantly reduce the threat of this disease."

What is CDC doing to address this needless loss of life? What would it cost to mount a successful campaign in these two areas?

Dr. DOWDLE. We are supporting several different projects. They are relatively small projects, but I think at the same time, highly effective projects in several different States. One State in particular has a highly successful prevention program for breast and cervical cancer, one that can be actually carried out in a number of other States as well.

The request that we had made earlier to OMB was for $35 million for the program.

Senator HARKIN. Thirty-five million dollars.

Dr. DOWDLE. That is correct.

Senator HARKIN. How does that compare?

Dr. DOWDLE. That money would be used nationally.

Mainly it is for information. It is for getting the information to the patient, getting information to the physician, getting the screening performed, and making certain there is diagnostic treatment follow-up.

PUBLIC HEALTH SERVICE

Senator HARKIN. Those are really all the questions I had except while other questioning was going on, I was reading this book on The Future of Public Health.

Is OMB sending up a request to have the big cut in NIOSH reinstated?

Dr. DOWDLE. Dr. Sullivan has sent a letter to OMB requesting that it be reconsidered, and stating that this is a major cut for an organization to take at any one time. The $26 million would hurt both extramural and intramural research, and the training program.

Senator HARKIN. Have you read this book?

Dr. DOWDLE. Yes, sir.

PUBLIC HEALTH SYSTEM

Senator HARKIN. What do we need to do? Do we need to reassess our public health system?

Dr. DOWDLE. I believe the headlines that came from that book saying that the public health in this country is in disarray may be a little excessive. I think that, in fact, we have some real heroes out there at the State and local levels, and we have some very, very competent people.

At the same time, I think that we certainly agree with the Institute of Medicine that we have a long way to go, a very long way to go, to bring State and local health departments up to the level necessary to provide the service that we think that this country deserves. We are working with the States to do whatever we can to provide capacity building.

We are also preparing a master plan in response to the IOM report with the States and with the local health departments to see what will be required and how it might be done.

PUBLIC HEALTH SERVICE CORPS

Senator HARKIN. Dr. Millar, as the clothes you are wearing indicate, the Public Health Service Corps is one of our uniformed services. How many personnel are in the uniformed services right now?

Dr. MILLAR. The total size of the corps? It is my understanding it's about 4,500.

Senator HARKIN. What has happened to the size in recent years? Has that been stable, gone up, gone down?

Dr. MILLAR. Basically, the number, I think, is close to stable. Because of the revitalization effort that Surgeon General Koop has undertaken, there have been changes in the distribution of those over the various ranks. There is clearly emphasis being put now on bringing in young officers and providing them with mobile careers that involve both geographic and organizational change. I would say at the bottom of the pyramid, things have increased a good bit. But I think overall the corps numbers have basically been the same for years.

Senator HARKIN. Are all those 4,500 doctors?

Dr. MILLAR. No; not at all. There are eight professional categories that are represented by chief professional officers. They range from pharmacists, nurses, sanitarians, physicians, engineers, and scientists. It is not by any means all doctors, nor even preponderantly doctors.

NATIONAL HEALTH SERVICE CORPS

Senator HARKIN. National Health Service Corps field placements. What does that mean? The budget last year was $39.8 million, and they are asking for a $19 million cut, cutting it in half to $20 million.

Dr. DOWDLE. That is a HRSA program, sir.

Senator HARKIN. Yes; does that have to do with the uniformed services?

Dr. DOWDLE. Well, it is a HRSA program which would not directly relate to the size of the corps.

Senator HARKIN. It doesn't have anything to do with the number of people who are in the corps and their salaries.

Dr. DOWDLE. No, sir.

Senator HARKIN. Now, where do you get your paycheck from, Dr. Millar?

Dr. MILLAR. The Department of Health and Human Services.

Senator HARKIN. All of the uniformed services is paid by the Department of Health and Human Services.

Dr. MILLAR. All of the commissioned officers in the U.S. Public Health Service are paid by a central payroll office. But there are seven uniformed services that are paid by the different departments where they work. The Coast Guard, the Public Health Service, National Oceanic and Atmospheric, and then, of course, the big Army, Navy, Air Force, Marines, are all paid in different places.

Senator HARKIN. They are not all part of the National Public Health Service Corps.

Dr. MILLAR. That's correct. We are one of the seven uniformed services of the United States.

Senator HARKIN. Doctors in the Navy are paid by the Navy; in the Army, by the Army, et cetera.

Dr. MILLAR. That's right. They are naval officers paid by the Department of Defense. Correct.

Dr. HINMAN. Senator, I think there may be some confusion in terms. The National Health Service Corps is a program for placing health care providers in underserved areas for limited periods of time. It is not the same as the commissioned corps of the Public Health Service, which is the uniformed service that Dr. Millar and I are members of. The National Health Service Corps serves a different function. Some of its members are commissioned officers, but it is, in essence, independent of the commissioned corps.

Dr. DOWDLE. And also to make sure we are clearly understood here, let me add that the salaries of the officers are paid from appropriations to the specific organizations. In other words, CDC pays the salaries of the commissioned corps assigned to CDC.

Senator HARKIN. How long have you been in the uniformed service?

Dr. MILLAR. One hundred years. [Laughter.]

That is why we wear these nice, little buttons this year. That is the centennial of the commissioned corps. The Public Health Service was initiated in 1798 as the U.S. Marine Hospital Service to take care of merchant seamen and sailors of the U.S. Navy. But the actual personnel system, called the commissioned corps, is 100 years old this year.

I have been in it a good part of those 100 years. [Laughter.]

PUBLIC HEALTH SERVICE

Senator HARKIN. I have to get a better handle on this.

If we have a public health problem out there in America, which evidently we recognize we do in the inner cities and the rural areas, that are genuine public health concerns, not just private, but genuine public health concerns, why isn't there an emphasis on utilizing the uniformed services to address that problem? You said there is a National Health Service Corps and there is a National——

Dr. HINMAN. Public Health Service.

Senator HARKIN. Public Health Service Corps. Why aren't some of the people in the uniformed services utilized for that purpose?

Dr. MILLAR. Well, the U.S. Public Health Service commissioned corps is definitely utilized for that purpose. For instance, we staff the Indian health service. We staff the Federal prison health service, the Coast Guard. All of those are beneficiaries of ours. And, indeed, the National Health Service Corps, which is a different program of the Public Health Service, does include commissioned corps officers. Some of them are and have been assigned in rural Appalachia, central cities, and places all over the country where they serve to provide health care services.

Senator HARKIN. You come under the jurisdiction of the Secretary of HHS.

Dr. MILLAR. That's right.

Senator HARKIN. Has that always been true?

Dr. MILLAR. Well, there hasn't always been a HEW or HHS. But since HEW was started, we have been part of that department.

Senator HARKIN. I wonder where you were before.

Dr. HINMAN. The Federal Security Agency.

Senator HARKIN. The Federal Security Agency?

Dr. HINMAN. I believe that is correct. Up until the formation of the Department of Health, Education, and Welfare in the Eisenhower administration.

Senator HARKIN. But it has never been under the Department of Defense?

Dr. HINMAN. No, sir; when the commissioned corps was formed in 1889, it was a part of the Department of the Treasury.

Senator HARKIN. It just seems to me there is something out there that appeals——

Dr. MILLAR. I would certainly encourage you to get to know the commissioned corps and all the issues about it because it is a vital and I think not clearly understood service.

For instance, we have just recently had commissioned officers down in the Brownsville area providing very real service to the Central American refugees who are hung up there waiting to see whether they are going to be admitted or not. We are, in fact, the people who are determining whether they have tuberculosis and providing medical care to them as they go through that process.

Commissioned corps people in the Public Health Service were vital participants in the global smallpox eradication program. We have people assigned in WHO, PAHO, and USAID. There really has been a global impact of the corps. I mean, I could give you a real sermon on this if you want it.

But I think that we badly need somebody to champion the cause of the commissioned corps within the Congress. I would encourage any interest you have in looking at the corps. It is a proud and I think a very irreplaceable resource, and we have not often been treated that way.

Dr. HINMAN. I would add also, Senator, that in terms of the public health system in the United States and local and State health departments, there are commissioned officers assigned from CDC working in State and local health departments at the present time, and at one time in the past, for example, Thomas Parran, who subsequently became Surgeon General of the United States, was assigned by the Public Health Service as the State health commissioner for the State of New York. So, there has been, over the years, an interplay between the public health structure at the local and State level and the Public Health Service.

Senator HARKIN. The Surgeon General is appointed by the President. Is that right?

Dr. DOWDLE. Yes.

Senator HARKIN. He serves at the pleasure of the President?

Dr. DOWDLE. Yes.

Senator HARKIN. Now, the most recent one, Dr. Koop, is he a member of the uniformed corps?

Dr. MILLAR. He is, yes.

Senator HARKIN. Was he before?

Dr. MILLAR. No; he was not. He was brought in from the private sector.

Senator HARKIN. You mean, if you are a surgeon general, you automatically become a member of the uniformed corps?

Dr. MILLAR. That is correct, yes.

Senator HARKIN. He just went from being a civilian to being an admiral.

Dr. MILLAR. He went from being a surgeon to being a surgeon general. That is correct.

Senator HARKIN. I thought he wore an admiral's stripe.

Dr. MILLAR. Our ranking structure parallels the Navy, and we are referred to by naval designations. That goes back to the saltwater tradition I mentioned earlier back in the beginning when we provided the medical care for the Navy as well as the merchant marines, also the shipboard inspections which was the other mainline ingredient of the early Public Health Service. It's a very strong saltwater tradition.

Senator HARKIN. Well, I have to get a better handle on it.

It just seems to me there is something out there that appeals to me in terms of addressing some of the comprehensive health care needs of this country that we may not be looking at. When we are thinking about restructuring the health care system—this is beyond the purview of this hearing, but there may be something there. I don't quite have a handle on it yet, but I'm getting there maybe.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

That's all I have. Thank you very much. I appreciate it.

We will have some other additional questions that we will submit for the record.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

PUBLIC HEALTH SYSTEM

Question. Dr. Dowdle, the Institute of Medicine recently released a report entitles "The Future of Public Health." The report of the Institute of Medicine indicates that about 43 million Americans or 18 percent of the population, do not have a physician, clinic, or hospital as a regular source of health care. The report concluded that "The current state of our abilities for effective public health...is cause for national concern..."

As you know, the community health centers and the National Health Service Corps are targeted to serve the medically underserved and the poor. It would seem to be useful to increase funding for the preventive health block grant and to provide funding for capacity building awards to states that have weak public health programs. Apparently, based on the Institute of Medicine's report, we come nowhere near meeting the health needs of this country.

Dr. Dowdle, do we need to reassess our public health system and its response to the health prevention and care needs of the country?

Answer. The Institute of Medicine report on the Future of Public Heaith is an important document. While people in public health may argue over the validity of one or another point, most agree that the Nation should be concerned about whether the public health system has the capacity to do all that is expected of it. A similar concern was expressed by the Presidential Commission on the HIV Epidemic regarding the impact of HIV on already overburdened public health departments. We agree that the IOM Report requires a thoughtful assessment of the ability of this system to respond to the Nation's prevention needs. Although we agree with the report, we know that there are many excellent people and programs within the State and local health agencies.

As the Department's lead agency for prevention, CDC is developing its plan for specific responses we can make to the findings of the report, especially in regard to capacity-building efforts we can undertake in helping States carry out the core public health functions defined in the Report and to plan and prepare for the year 2000 objectives.. We will coordinate our work with a number of nongovernmental groups now reviewing the recommendations of the Report.

ADEQUACY OF BUDGET REQUEST

Question. Dr. Dowdle, although the overall fiscal 1990 budget request for the Centers for Disease Control increases by $68,799,000, when you subtract the funding for AIDS you find that your budget has actually decreased by $26,071,000, or by about 4.5 percent. This is a substantial decrease in funding for an agency that is responsible for much of the public health in this country.

We spend over $7 billion a year on basic research at NIH. It seems to me that CDC has the primary responsibility for disease prevention; CDC has the responsibility for implementing what we now

know; for getting out what we learn from NIH research. Do you have enough funding to meet this mission?

Answer. The 1990 budget requests $573.6 million for CDC's non-AIDS activities. Of course, there are always more opportunities for program expansions in all areas of Preventive Health Services than resources to support them. However, within the funds available, CDC is supporting those projects which it believes are the highest priority. For any further program increases beyond those priorities included in the 1990 President's budget, no further offsets have been identified.

DISABILITY PREVENTION

Question. The Disability Prevention program provides assistance to states and communities to enable them to focus and coordinate efforts to prevent secondary disabilities, permanent disabilities as a result of injury, and developmental disabilities. Persons with a disability are at greater risk for developing secondary disabilities which further limit their ability to live independently. There are varying estimates on the number of disabled Americans--those estimates range from 20 to 50 million. However, the majority of disabilities occur in persons under 35 years of age, at a national cost of about $120 billion per year. In FY 1989, $3.8 million was appropriated for disability prevention programs.

What has been the response to this program, i.e., how many applications did you receive for that $3.8 million in funding, and how many programs have been funded?

Answer. In FY 1988, with only 45 days to develop plans and submit proposals, 26 States submitted applications totalling $7.1 million for State-based projects. We were able to fund 9 of these projects totalling $2.12 million. In addition, 15 academic institutions submitted applications for Demonstration/Epidemiology projects totalling $2.7 million. Four of these were funded at a level of $708,000.

Question. Do you feel that there is a need for this program, and that it can make a difference?

Answer. Yes, there is a need and yes we feel this program can make a difference. Over 35 million Americans have a disability and the federal government spends over $60 billion each year for disability services. For some disabilities, effective preventive interventions are known. In addition to lead screening and environmental lead abatement, effective interventions include screening of newborns for phenylketonuria and congential hypothyroidism, proper use of seat belts, air bags, and motorcycle and bicycle helmets, tighter enforcement of drunk driving laws, banning unsafe toys and sports equipment, making playgrounds safer and having stricter driving regulations. For other disabilities, these interventions need to be identified.

One of the purposes of this program is to assist States in building capacity to implement known interventions. We also want to increase the knowledge base about disabilities prevention in general, but particularly where interventions have not been

identified. We feel this program can be a highly effective instrument to prevent the occurrence of and reduce the severity of disabilities and their complications, as well as reduce expenditures.

INJURY PREVENTION AND CONTROL

Question. Injury outside the workplace is the leading cause of disability among persons of all ages and the leading cause of disability among young persons. Injuries kill more Americans aged 1 to 44 than all other diseases combined. In 1986, 150,000 people lost their lives. The fiscal year 1990 budget recommends that the Injury Control State Programs and the Prevention Centers Program both be folded in to the Preventive Health Services Block Grant.

In your professional judgment will this consolidation advance our shared interest in reducing injuries and disabilities in America?

Answer. I think we need to proceed very carefully as we further develop and implement a program to address such a recently recognized priority health problem as injury.

Injury, as you know, is in its infancy as a recognized public health problem. Yet injury is one of the leading preventable public health problems in America today.

Because injury has only recently been recognized as a priority public health problem, it may be premature to transfer funds to the block grant. Our partners in States and communities and universities have not had sufficient time to build constituencies and develop injury as a priority issue. States find themselves in the position of needing technical assistance in developing approaches to the injury problem. They especially look to us at the national level to create interest in this priority health problem and to assist them in bringing injury to the forefront among other competing priorities.

It is most appropriate for CDC to provide seed money for these State efforts which in turn can provide model programs for translating to other States. In the area of Injury Prevention Centers it is particularly important to focus our resources where we will get the greatest return. All States do not have the same capability in their universities to provide the needed expertise. Open national competition for available research funds would better allow us to address the injury problem.

PREVENTIVE HEALTH BLOCK GRANT

Question. The fiscal year 1990 budget also recommends that injury control, prevention centers, and the diabetes and tuberculosis grants be folded into the Preventive Health Block Grant. I am not sure that this is a good idea as we lose the ability to focus in on these special problem areas.

I understand that this is not a CDC recommendation, but is an OMB idea.

What is your professional position on this proposed consolidation of these programs?

Answer. The block grant is an important source of Federal support for health department activities. It is designed to give States maximum flexibility in using Federal funds to address problems which they identify as high priorities. A continued and strong emphasis on these four programs will require a committed partnership between the Federal government, State and local governments, the private sector, voluntary organizations, and patient advocacy groups. Considerable progress has been made in forging these partnerships which will have to be maintained if the goals of these four programs can be achieved. Efforts will be made to minimize any potential for negative impact on these important activities. The consolidation of these programs into the Preventive Health Service Block Grant was intitally proposed by the Department.

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

Question. The fiscal year 1990 request for occupational safety and health shows a $25.8 million, or 35 percent, reduction.

Dr. Dowdle, since I have become chairman of this subcommittee I have received more mail on this issue than any other single issue.

I understand that Secretary Sullivan wrote OMB last Friday to request that the must be restored.

We have been told that OMB intends to send up a formal request to restore this cut. Is that correct?

Answer. A budget amendment request to restore the reduction in NIOSH has been forwarded by the President to the Congress on May 18, 1989.

BREAST AND CERVICAL CANCER

Question. Each year there are more than 50,000 women who die from breast and cervical cancer.

50,000 people dying each year is equivalent to 250 Boeing 757 airline crashes, where the planes are full and all passengers are killed.

On page 42 of your budget justification, it states,". . . the fact that women die of cervical cancer is troublesome since medical technology exists to significantly reduce the threat of this disease."

What is CDC doing to address this needless loss of life?

Answer. CDC resources for breast and cervical cancer prevention are directed at improved surveillance, epidemiologic analysis, and the development and evaluation of intervention efforts. CDC's work is being conducted in cooperation with State health departments, voluntary and professional organizations, and other Federal agencies.

CDC is assisting selected States to translate effective technologies into systematic screening programs. These programs focus on screening high-risk populations, providing education to the public and to health care providers, and assuring the

highest quality of the screening test. For example, in 1988, CDC initiated support to the State of Maine to develop a comprehensive breast cancer screening program that would ensure access to quality screening at an affordable cost for women aged 40 and over.

In 1987, the CDC-coordinated Behavioral Risk Factor Surveillance System began collecting information on the use of mammography screening in participating States. Among all participating States, the range in the proportion of women aged 40 and over who have had a mammogram in the last year was between 15% and 46%, with a median of 30%. State-specific information on mammography use will enable participating States to better plan and evaluate breast cancer screening programs.

CDC is working with other Federal agencies to address the issue of the quality of the screening tests for breast and cervical cancer. For example, CDC is assisting the Health Care Financing Administration (HCFA) to establish cervical cytology laboratory standards and is working with the Food and Drug Administration, the American College of Radiology, and others to establish quality assurance guidelines for screening mammography.

Question. What would it cost to mount a successful campaign against breast and cervical cancer?

Answer: It is estimated that 40,000 women die from breast cancer and 7,000 from cervical cancer each year. A large portion of these deaths are needless as the knowledge and technology currently exist to prevent them. The key to reducing unnecessary illness and death from these cancers is to ensure early detection and appropriate follow-up for women with positive mammography and Pap smear test results. We must increase the number of women who are screened for breast and cervical cancer, ensure the accuracy of screening tests, and provide timely and effective interventions.

CDC has initiated cancer control programs in several States to address these challenges. Progress has been made in identifying barriers to screening, quality assurance, diagnostic follow-up, and treatment. For example, preliminary data indicate that changes in the medical care system are needed to ensure that Pap smears are included during routine medical visits and that women with abnormal tests receive appropriate care. Also, CDC activities have clarified the design of national quality assurance programs for mammography screening and cervical cytology.

A successful comprehensive campaign against breast and cervical cancer would necessarily have to address the same issues that CDC is currently exploring through its State-based activities. Such a campaign would have to ensure that screening services were available to all women; that both health care providers and the public were educated on the value and recommended frequency for screening; that the tests were of the highest possible quality; and that women with abnormal results received prompt diagnostic follow-up and treatment.

There is currently no such campaign in place at the national level. However, it is estimated that the cost of launching and implementing such a campaign active in all 50 States would require approximately

$255 million. If Federal funding were provided to cover 50% of the cost of screening services for women without health insurance coverage, the cost estimate would be $418 million. Cost projections are based on the best scientific judgment of CDC scientific staff. No request has been included in the 1990 President's Budget. This proposal has not been reviewed by the Administration in comparison with other priority areas including AIDS, Drug Abuse, Homelessness, and the need to reduce the Federal budget deficit.

PREVENTION CENTERS

Question. The budget submitted by President Reagan proposed folding injury prevention, diabetes and TB grants to the States, and Prevention Centers into the block grant.

Aren't your prevention centers established in schools of public health?

Answer. Currently, prevention center funding has been directed to five schools of public health, but schools of medicine and osteopathy are also eligible to apply.

Question. Would a State fund a center at a school of public health?

Answer. If the concept of the prevention centers falls within the needs and priorities developed for the Preventive Health Block Grant Program by a respective State, a prevention center(s) could be funded. Where such a prevention center would be established within a State would be left up to the State.

Question. If you divide the $2 million for prevention centers by 50 States, aren't you diluting the funds to the point that no centers would be funded?

Answer. Not necessarily. The States have considerable flexibility in the expenditure of block grant funds. Accordingly, a State funding a prevention center has the option to allocate an appropriate amount for a prevention center program.

TB FUNDING

Question. Is TB an equal problem in all States, and if not, why are you proposing to give funds to all States?

Answer. No, TB is not an equal problem in all States. Our data show that tuberculosis is retreating into defined focal pockets within the United States. Among HIV-infected and HIV-uninfected populations, tuberculosis continues to disproportionately affect the socioeconomically disadvantaged, including racial and ethnic minorities, foreign-born persons, the elderly, and the homeless; also persons in correctional institutions. Those areas having large populations in these groups generally have a greater tuberculosis control problem. However, currently about 37 of 57, or 65%, of all potential State and territorial grantees are awarded funds under the existing categorical TB control program. Under the budget proposal, each State with recognized TB problems could use the flexibility of the block grant to continue to focus on the problems.

Question. Will this proposal have a negative impact on TB control efforts?

Answer. The block grant is an important source of Federal support for health department activities. It is designed to give States maximum flexibility in using Federal funds to address problems which they identify as high priorities. Elimination of tuberculosis from the United States will require a committed partnership between the Federal government, State and local governments, the private sector, voluntary organizations, and patient advocacy groups. Considerable progress has been made in forging these partnerships which will have to be maintained if elimination of tuberculosis is to be achieved. Efforts will be made to minimize any potential for negative impact on these important activities.

DIABETES

Question. Are we currently funding diabetes projects in all States?

Answer. No. The Centers for Disease Control, is currently funding cooperative agreements in 29 States and 1 Territory, or about 50 percent of the total pool of potential State and territorial applicants.

Question. By distributing the $4.9 million to all States, an average per State of less than $100,000, do you think it will have a greater impact on improving the morbidity and mortality rates among diabetic persons?

Answer. The block grant is an important source of Federal support for health department activities. It is designed to give States maximum flexibility in using Federal funds to address problems which they identify as high priorities. Effective diabetes control program will require a continued coordinated partnership effort from all facets of the public health community. Considerable progress has also ready been demonstrated and the States utilizing the block grant will have the discretion to support and strengthen the programs as needed.

RADIATION

Question. How did CDC get involved with radiation issues? Why have you started working on radiation problems?

Answer. CDC began developing programs in general environmental health and chronic diseases in the early 1970's. Since then, CDC has periodically been asked by various groups (primarily affected citizens, and State and local health departments) to assist in evaluating the health implications of selected radiation problems. These included: evaluating the potential for leukemia and other health effects in veterans who served at the atom bomb test site in Nevada; the emergency response to the Three Mile Island nuclear reactor incident; assistance to ATSDR in assessing the health risks from radiation at selected Superfund National Priorities List sites; assistance to EPA in developing a national strategy for radon, and evaluation of health risks in communities surrounding selected DOE

nuclear facilities. CDC has been called upon repeatedly to assist in evaluating these problems. This suggests to us that there is some gap or void that CDC is being called upon to fill with regard to public health responses for environmental radiation issues.

Question: Does CDC have formal, designated responsibilities related to radiation, and if so, what resources have you had to carry out those responsibilities.

Answer. In 1979, as a follow-up to CDC participation in the DHHS response to Three Mile Island, CDC was designated as the lead agency within the PHS for coordinating the PHS response to radiation emergencies. During the past 10 years a small number of individuals, working part-time on these radiation issues with primary responsibilities elsewhere, have carried out these activities for CDC. In 1989, we received an additional $1.5 million and 3 FTEs to work on the study of the health effects of radiation exposure at the DOE Hanford Nuclear Facility in the State of Washington.

Question. It is clear that it is very difficult to maintain sustained activities in a program area that lacks ongoing funding and resources and where individuals are assigned on a part-time, adhoc basis. What is the minimum needed for you to establish a core program to deal with environmental radiation issues?

Answer. CDC's current staff working part-time on radiation concerns serves as its core program to allow CDC to respond to the highest priority environmental radiation issues. Additional staff, perhaps 8 - 10 FTE, with further skills in radiation epidemiology, health physics, environmental monitoring and radiation dose assessment, and statistics and computers could always be used effectively. However, the 1990 budget does not request funding for such expansions in this area, and no offsets have been identified to accommodate any such increases beyond the priorities included in the 1990 President's budget.

CHLAMYDIA CONTROL PROGRAM

Question . We understand that Chlamydia trachomatis is the most common sexually transmitted bacterial pathogen in the U.S. today, causing an estimated 4 million acute infections annually with serious complications and sequelae in women and children. What is the status of CDC's efforts to establish a national chlamydial control program and what progress has been made in implementing CDC's national policy guidelines for the prevention and control of chlamydia infection?

Answer. CDC has made substantial progress in the development of a national chlamydia prevention and control program. States have been encouraged to require reporting of chlamydia associated disease and to transmit appropriate surveillance data since January 1984 when CDC implemented a surveillance system for collecting and monitoring reported cases of chlamydial infection. This system requires State reporting laws and or regulations to provide the necessary support for prevention activities. Such laws promote and legitimize the involvement of public health authorities in assuring adequate individual patient management, including referral of sex

partners, and may facilitate other activities such as screening and education. By the end of FY 1988, 30 States had developed reporting laws or regulations, 51 STD project areas have public laboratory capability for the diagnosis of chlamydia trachomatis, 54 treat chlamydia in STD clinics, 49 provide patient counseling services, and 42 have at least one city or county STD program that offers all of the above services.

Expenditures for the prevention of chlamydia have been increased substantially since 1985. In FY 1986 approximately $5.8 million dollars were devoted to chlamydia prevention and control. This figure was increased over 50 percent to $8.8 million in 1987 and increased to almost $9 million in FY 1988. In FY 1989, an additional $8 million of STD Grant Funds will be allocated for the prevention and control of chlamydia trachomatis infection. This will allow the development of comprehensive chlamydia prevention and control programs which will include screening of those at highest risk to identify chlamydia treatment, counseling, testing, and partner notification activities for those that are positive, and education programs for those in high risk areas.

In addition, CDC will continue to support research, demonstration, and disease intervention projects for the prevention and control of chlamydia . These projects are designed to identify and evaluate more effective diagnostic techniques and therapeutic regimens and to better define the epidemiology of chlamydia among those at greatest risk--pregnant women and their offspring, women with salpingitis, and adolescents. Research will be conducted to assess the most cost effective methods for detecting and treating asymptomatic infections which we believe to be the key to more effective control.

Question. We understand the Chlamydia trachomatis is the most common sexually transmitted bacterial pathogen in the U.S. today, causing an estimated 4 million acute infections annually with serious complications and sequelae in women and children. What is the cost of implementing these measures.

Answer. The 1990 budget request of $68.2 million for STD grants to States includes $17 million for activities devoted to chlamydia prevention and control. This is an increase of $9 million over the 1988 level of support for chlamydia. Of course, there are always more opportunities for program expansions in all areas than resources to support them. Within the funds available, CDC is supporting those projects which it believes are the highest priority. For any further program increases beyond those included in the 1990 President's budget, no further offsets have been identified. If additional resources were available, CDC estimates that it would cost an additional $55-60 million a year to establish a comprehensive chlamydia screening program for those asymptomatic individuals who are at risk and to provide expanded disease intervention follow-up with personnel appropriately trained in STD partner notification and counseling. With this level of grant support, CDC could utilize an additional $3.3 million to support research and technical assistance. The cost of the grant program could be expected to decrease if the cost of laboratory tests were to decrease and as targeting of screening activities was effected.

GENITAL ULCERS

Question. A number of studies have shown an association between syphilis, chancroid, and herpes and increased risk of infection with HIV. What measures are being taken nationwide to prevent and control genital ulcer disease, particularly in high-risk groups such as intravenous drug users?

Answer. It is correct that sexually transmitted diseases, especially those which cause genital ulcers, increase the risk of acquisition and transmission of HIV infection. The current resurgence in the United States of the STD causing genital ulcers--primary and secondary syphilis, chancroid, and genital herpes, has occurred primarily among minority heterosexuals. This upsurge has created a critical need to target STD control measures to this population. Primary and secondary syphilis have increased by 17 percent in 1988 over 1987, and represent the largest number reported in any year since 1949! Chancroid increased by 28 percent during the same period. Genital herpes is the main cause of genital ulcers in the United States. Most of these infections are occurring in minority, inner-city, heterosexual populations, the same groups that are at high risk of HIV infection associated with IV drug use.

CDC strategy for the prevention and control of genital ulcer disease is divided into four components including research, surveillance, disease intervention/program operations, and training. The approach of research is to investigate the link between illegal drug use, prostitution, genital ulcer infections, and their implications for HIV transmission, and to conduct epidemiologic studies to determine the risk of acquisition of HIV caused by genital ulcers. Surveillance activities seek to develop a comprehensive automated STD data management information system at both the National and State levels, to expand and refine syphilis surveillance activities in each STD project area to assure that they include screening of high risk populations, and to institute a genital herpes surveillance system. In the area of disease intervention/program operations, CDC provides grant awards to all State and selected project areas to support traditional STD control strategies including screening, laboratory surveillance, partner notification, preventive treatment, and primary prevention, including health education/risk reduction activities associated with genital ulcer disease. This latter activity also includes the redefinition of goals and priorities at the national level which would seek to design and conduct coordinated and culturally sensitive information outreach efforts to those that are in high-risk and hard-to-reach subpopulations, including IV drug users. Training is geared to provide clinicians with the latest information on the diagnosis, treatment, and management of genital ulcer disease and to expand the nationwide training capability to develop an entry level as well as an experienced intervention staff.

SEXUALLY TRANSMITTED DISEASES

Question. A number of studies have shown an association between syphilis, chancroid, and herpes and increased risk of infection with HIV. What is the cost of implementing these measures?

Answer. The total costs for this program for FY 1990 are estimated to be $17.1 million in grants and $3.5 in direct operations. The breakdown by individual diseases are estimated to be approximately $16.6 million in grants and $2.35 million in direct operations for syphilis, $.3 million in grants and $.7 million for herpes and $.2 million in grants and $.4 million in direct operations for chancroid.

RESISTANT GONORRHEA

Question. We understand that gonorrhea continues to be the number one reportable communicable disease in the U.S. although a 34 percent decrease in total cases has occurred since 1981. During FY 1988, however, the problem of antibiotic resistance increased in size and complexity and a number of States reported prevalence levels of epidemic proportions. What measures are being taken nationwide to prevent and control resistant gonorrhea infection and what is the cost of full implementation?

Answer. Although gonorrhea morbidity has decreased 34 percent since 1981, there is considerable concern over the validity of this decrease. While it is likely that a substantial portion of this decrease reflects the cumulative effect of gonorrhea prevention efforts, it is also true that some areas have reduced their screening efforts. In some large cities, gonorrhea is actually increasing, especially among inner-city minority populations. Seven States reflected increases in FY 1988 as compared to FY 1987. On the other hand, 43 States showed decreases in gonorrhea cases in FY 1988.

Over the past few years, there has been increasing concern over the problem of antibiotic resistance in N. gonorrheae. Compared to other parts of the world, we are still in relatively good shape. However, the proportion of gonococci having resistance has risen steadily since 1980. For example, 45 percent of gonococci nationwide have some resistance to penicillin or tetracycline, and five percent of all gonococci are resistant enough to result in failure of traditional penicillin therapy (i.e., PPNG).

Control strategies for resistant Gc have two specific objectives in addition to those of traditional gonorrhea control. First, we are recommending increased laboratory surveillance for antimicrobial resistance. Second, in areas with a resistance problem, we are recommending changing therapy for all gonorrhea to drugs such as ceftriaxone, which are effective against resistance infection. These drugs are 5-7 times more expensive than traditional therapies. Because of the widespread prevalence of antimicrobial resistant Gc, the number of areas which will have to change therapy will probably increase.

The cost for a comprehensive program for prevention and control of resistant gonorrhea in the United States would be estimated to cost $52 million in grants and $3 million in program funds. However, these funds have not been requested in the FY 1990 Presidents Budget. No offsets have been identified to accommodate such increases within the current budget/deficit reduction targets.

CHRONIC DISEASE PREVENTION

Question. Chronic diseases place an enormous economic and emotional burden on Americans in all walks of life.

What is CDC doing to address this problem?

Answer. In October 1988, CDC established the Center for Chronic Disease Prevention and Health Promotion to provide a centralized focus for efforts directed at chronic disease. The mission of this new center is to plan, direct, and coordinate a national program for the prevention of illness and death due to chronic diseases and to promote healthier lifestyles among Americans.

In fiscal year 1988, CDC implemented a variety of projects to prevent or control chronic disease. These projects build on CDC's expertise and experience in the areas of surveillance, epidemiologic investigation, and the development of disease intervention programs.

In the area of surveillance, CDC is assisting 40 states and the District of Columbia in tracking risk factors for heart disease such as smoking, hypertension, sedentary lifestyle, obesity, and elevated cholesterol. The Behavioral Risk Factor Surveillance System is the foundation for state chronic disease prevention programs. For example, Michigan used the data on smoking to secure State funds for a major health promotion program.

A recent CDC epidemiologic study investigated trends in cigarette smoking among Hispanics in the U.S. The study found that while cigarette smoking is decreasing among Hispanic men, smoking among Hispanic women has not decreased and may well have increased. This type of finding has important implications in successfully targeting intervention strategies toward selected populations. In large part, the major chronic diseases are caused or aggravated by a common factor: poor health behavior choices. The choices of whether to smoke, whether to get regular exercise, whether to eat a proper diet, whether to get regular diagnostic screenings (e.g, for hypertension; cervical, breast and colon cancer) all contribute significantly to an individual's chances of developing a chronic disease. CDC's intervention efforts are aimed at preventing chronic disease through educating Americans on the proven benefits of a healthy lifestyle and preventive health care (e.g., screening for early detection, and regular health care to reduce complications of existing disease).

Question. What more could CDC be doing to prevent unnecessary deaths and illness due to chronic disease?

Answer. CDC has the institutional skills and expertise, and experience to support chronic disease control programs in State and local health departments, to translate scientific and programmatic knowledge into coordinated public health programs capable of reaching large numbers of people. Community cardiovascular disease interventions, screening programs for early detection for breast and cervical cancers, comprehensive school health curricula, and diabetes control projects have all demonstrated the potential to significantly reduce the impact of chronic diseases. The publication "Closing the Gap: The Burden of Unnecessary Illness,"

(documentation and intervention strategies resulting from the Health Policy Consultation of the Carter Center of Emory University, November 26-28, 1984, Atlanta, Georgia) provides information on recent studies indicating that nearly one-third of cancer deaths, almost one-half of deaths due to cardiovascular disease, and over one-third of the debilitating complications of diabetes can be prevented through the widespread application of currently available but as yet largely unapplied knowledge.

This could be addressed by the following:

- o CDC could mobilize a coalition of public and private agencies committed to a common agenda for the prevention and control of chronic disease.

- o Surveillance capability to monitor trends at the local, State, regional, and national levels could be enhanced in order to prioritize prevention efforts, to justify and focus resources, and to evaluate the impact of multiple, broad-based interventions.

- o Training to State and local health agencies could be expanded to facilitate widespread implementation of effective intervention strategies.

- o Technical assistance could be provided in planning, marketing, implementing, and evaluating chronic disease prevention and control programs.

As resources become available in the future, CDC expects to expand its efforts in these areas.

PREVENTION CENTERS

Question. How many prevention centers are you funding?

Answer. Currently we are funding five prevention centers.

Question. Are they important to the delivery of prevention activities?

Answer. These centers undertake research with a public health purpose to disseminate proven, cost-effective public health interventions regionally and nationally. They assist the public health system in establishing priorities, using scientific data in decision making, and introducing new approaches into prevention practices. Prevention centers are at this time researching various issues involving lifestyles, stress, and social impact on health.

Question. Are more centers needed to maximize your prevention efforts?

Answer. There is much prevention research that still remains to be done and with additional centers, prevention activities could be expanded to cover a wide diversity of issues relating to the future health of our citizens. Prevention centers emphasize outreach to State and local health departments and the private medical community to maximize the contribution of prevention and to increase the

implementation of research fundings. Additional centers performing such efforts could lead to greater use of effective interventions.

CHILDHOOD PREVENTIVE MEASURES

Question. Children in the U.S. today are subject to intense social pressure. How can we prevent children from adopting risky health behaviors such as smoking, alcohol use, drug abuse, and behaviors related to HIV and AIDS?

Answer. Almost three-quarters of all deaths among American youth aged 1-24 is due to only four causes: motor vehicle crashes, all other accidents, homicide, and suicide. In addition, each year about 800,000 teenage females became pregnant unintentionally; and about 2.5 million teenagers are infected with a sexually transmitted disease (STD), not including HIV. Most of these health problems result from a limited number of behaviors established during youth that result in morbidity and mortality during youth and also during adulthood. These behaviors include: failure to use seatbelts; drinking or drug use and driving; drinking or drug use that contributes to accidents other than motor vehicle, as well as to homicide and suicide; and unprotected sexual intercourse that results in unintended pregnancies and STDs, including HIV infection.

Among all age groups combined in the United States, nearly two-thirds of all deaths is due to only two causes: heart disease and cancer. These health problems to a significant degree result from a limited number of behaviors, often established during youth, but which generally do not result in morbidity or mortality until adulthood. These behaviors include: use of tobacco; excessive consumption of fat, calories, and sodium, and insufficient consumption of fiber; and insufficient exercise.

There is one important means this Nation could employ to reduce risk behaviors among young people, and the adults they will become. The Nation could help schools in every community to implement planned and sequential, kindergarten through grade 12, programs of comprehensive school health education. These programs can help young people at the earliest ages understand how their behaviors will influence their health; how to make decisions that will affect not only their health but the health of others; and, how to resist persuasions to engage in behaviors that will threaten their health. Such programs are planned and implemented with broad parental and community participation. They integrate education about a broad range of health topics when it is developmentally appropriate to address these topics; and help students develop the interrelated skills they will need to avoid, for example, alcohol, tobacco, and drug abuse; unintended pregnancies and sexually transmitted diseases, including HIV infection; and heart disease and cancer associated with excessive consumption of dietary fat. Our schools could assure that young people have the knowledge and skills they will need to protect their own health in the twenty-first century.

AIDS PREVENTION

Question. The budget does not show any CDC funding for intravenous drug use, yet the justification reflects activities in

this area for minorities and at testing and counseling site. What percentage of CDC's prevention resources are targeted at the persistent problem of HIV infection in the drug-abusing population? How are these efforts coordinated with ADAMHA?

Answer. In fiscal year 1988, $15 million in CDC's HIV prevention funds was targeted to IV drug users receiving counseling, testing, and partner notification services in drug treatment centers. Currently, $20 million is available and $25 million has been requested for fiscal year 1990, representing approximately eight percent of CDC's total HIV Prevention budget. IV drug users also receive similar services through STD and TB clinics, family planning centers, and women's health services. In addition to the funds exclusively targeted to IV drug users, CDC supports a number of program efforts which also address HIV prevention in that population. For example, State and local HIV Prevention and Surveillance Programs and HIV School Health Education Programs, Community Demonstration Projects, and Perinatal AIDS Prevention Projects stress HIV prevention related to IV drug use.

In addition, the fourth phase of the National AIDS Information Campaign, "Parents and Youth", was launched on May 25, 1989. This phase is an extention of the "America Responds to AIDS" effort and contains messages which address IV drug use and related HIV prevention for our young people.

CDC, NIDA, and ADAMHA share project-related HIV prevention information on an ongoing basis and occasionally conduct joint site visits. CDC also provides copies of appropriate cooperative agreement applications to NIDA for review and comment. In fiscal year 1989, CDC provided NIDA with copies of HIV Prevention and Surveillance cooperative agreement applications from the 24 jurisdictions with the highest number of reported AIDS cases.

CDC provides funds for HIV counseling and testing in drug treatment centers through the HIV Prevention and Surveillance cooperative agreements with State and local health departments. To ensure coordination at the local level, CDC has requested that cooperative agreement funding recipients collaborate with drug abuse agencies in developing plans to address HIV prevention among IV drug users in drug treatment centers.

In addition, through an interagency agreement with NIDA, CDC provided $1 million in fiscal year 1988 for expanded HIV counseling and testing services in those drug treatment centers participating in NIDA sponsored non-blinded HIV seroprevalence surveys.

AIDS - EDUCATIONAL EFFORTS

Question. What funding levels is CDC providing in FY 1990 for State and local school districts on AIDS prevention?

Answer. In FY 1990, CDC will provide approximately $32 million in support to State and local school districts for school and college-related HIV education activities.

Question. How effective were the educational efforts aimed at the general public, including the mass mailing and the October AIDS Awareness Month in 1987 and 1988?

Answer. The Public Health Service, through CDC, initiated the overall public information program in October 1987 under the theme "America Responds to AIDS." The program has been extremely successful. Media and newspaper market data through 1988 indicate that $26 million in free public service time has been contributed to the HIV prevention program and virtually 100 percent of American homes have received television and other media messages.

CDC learned much from the development and distribution of a national mailer on AIDS. This mailer represented the largest public health mailing ever, and afforded us a unique learning experience.

The national household brochure mailing was accomplished in May and June of 1988. Distribution of 112 million copies of "Understanding AIDS" in English, Spanish, and in Braille was completed by June 15. In addition to the household mailing, copies were also provided to the military, correctional institutions, shelters for the homeless, and to Federal employees assigned to posts overseas. Copies continue to be requested from our National AIDS Information Clearinghouse. Translations in Chinese and Portuguese are currently being distributed. The U.S. Government Printing Office and the U.S. Postal Service, as partners with the U.S. Public Health Service, contributed significantly to making this a successful endeavor.

The public responded very favorably to this brochure. Two immediate measures of response were in place--calls to the National AIDS Information Hotline and letters to the National AIDS Information Clearinghouse. In the period concurrent with the mailout, June 1988, over 200,000 calls were received at the Hotline compared with the previous monthly averages of 100,000. Many of these calls were to the new Spanish Hotline whose telephone number was advertised for the first time in the mailer. A third assessment was the monthly survey of the National Center for Health Statistic's National Health Interview Survey which provided pre- and post-mailer data. This survey was used to answer these questions--who received the brochure, who read it, and what impact did it have.

Approximately 63 percent of all persons interviewed in the National Health Interview Survey remembered receiving the brochure, suggesting that the brochure was received by approximately 111 million individuals. There was a decrease in the number of individuals who recalled receiving the brochure as time progressed. Almost 8 out of 10 who received the brochure read it (79 percent), and approximately 6 out of 10 (60 percent) read all or almost all of the brochure. The overall readership was approximately equal among all age groups and among whites and blacks, but was greater among better educated individuals. Measurements of brochure impact suggested that 3 out of 10 individuals who read the brochure said that it gave them new information. Those individuals most likely to get new information or have questions answered were the most difficult to reach, including young blacks, and those with less than a high school education. Almost 4 out of 10 individuals who received the brochure discussed it with other family members.

In October 1988, the second AIDS Awareness Month introduced public information materials addressing the issues of sexually-active adults with multiple partners and women at risk. The level of public service time given these materials was maintained. Other evaluation measurements are still being assessed for this period.

AIDS COORDINATION

Question. What are CDC's roles in coordinating its neuroscience and behavior, vaccines, and blood and blood products, activities with ADAMHA, NIH, and FDA?

Answer. AIDS-related behavioral research at CDC has general objectives to monitor AIDS-related risk behaviors in high-risk groups, and to delineate social or behavioral risk factors related to both HIV transmission and progression to AIDS. Also, CDC behavioral scientists serve as consultants or committee members for many projects at National Institutes of Health including the Psychosexual Assessment Working Group at the National Institute of Mental Health; the AIDS Working Group at the Heart, Lung, and Blood Institute; and an advisory panel for the National Institute of Child Health and Human Development. These efforts permit CDC scientists to coordinate their activities with colleagues at NIH, thus reducing redundancy in projects and opening up opportunities for mutual collaboration.

CDC conducts studies of: the natural history of transfusion-associated HIV infection in adults and children; the heterosexual transmission of HIV from infected transfusion recipients to their partners; the characteristics of persons reported as having transfusion-associated AIDS. CDC continues to monitor the number of persons infected with HIV after receiving transfusions screened negative for HIV antibody. In addition, CDC is interviewing blood donors positive for HIV-antibody in 26 blood centers across the country to understand why persons at risk for infection continue to donate blood, and to develop better programs to prevent their donation in the future. CDC also evaluates new methods to test for HIV infection, including studies of the polymerase chain reaction, latex agglutination test, and the HIV antigen assay. The study of the HIV antigen assay as a screening test for 500,000 blood donations is a collaborative project with the NIH and the FDA. Data from other CDC projects related to transfusion are exchanged on a periodic basis through regularly scheduled conference calls with the FDA and at the biannual meeting of the NHLBI Advisory Committee on AIDS.

CDC collaborates with NIH and FDA in studying, defining, and evaluating HIV as it relates to the development of a broadly protective vaccine against the virus. CDC is also involved in developing possible new animal models for the evaluation of potential HIV vaccines.

GRANTEE ASSISTANCE

Question. What assistance does CDC provide cooperative agreement grantees when they experience difficulties establishing HIV counseling and testing sites?

Answer. CDC project officers provide ongoing technical assistance to individual project area coordinators, managers, and directors to insure that cooperative agreement recipients have the latest information and the most current recommendations regarding their program operations, including those related to the establishment and management of HIV counseling and testing sites. In addition, many of the larger project areas have direct CDC assignees participating, or assisting, in HIV program management matters, while other project areas consult CDC employees who are assigned locally and function in similar STD program capacities and who can provide technical assistance regarding the establishment of HIV counseling and testing sites.

Question. How does CDC assure itself that cooperative agreement grantees select the most appropriate locations for HIV counseling and testing sites?

Answer. Primary assessment of whether education agency and/or organization cooperative agreement recipients select locations for providing services that are likely to reach those most at risk for HIV infection is made during the application review process. Applicants from the State education agencies provide data on the incidence of reported cases of AIDS and STDs, and reported pregnancies among young people in their jurisdictions. This information forms the basis for establishing priorities in the school districts within their States or cities. Data may also include reports of other risk factors. During the application review process, an assessment is made to determine if priority areas within their jurisdictions are chosen based upon these data related to risk for HIV infection.

Health agency and community-based organization cooperative agreement recipients are expected to document the extent to which services, such as, HIV antibody counseling and testing services are accessible to high risk populations. This information is studied and compared with what is known about the area's geography and where populations at high risk for HIV are concentrated.

In addition, CDC assigns project officers to work with these HIV cooperative agreement recipients who are familiar with the State/locality having held similar responsibilities relative to STD control project grants. In many places the members of high risk populations for HIV infection are the same persons at high risk for STD and often use the services created for controlling such diseases. These project officers conduct site reviews to assess the scope and quality of these services and verify their accessibility.

AIDS - CENTRALIZED PROGRAM

Questions. Does CDC plan to keep the AIDS program centralized, or will it include the regional offices in AIDS monitoring, similar to what CDC has done to monitor State and local health department efforts to control sexually transmitted diseases?

Answer. At the present time, CDC plans to keep the AIDS Program centralized. Where appropriate, however, the HHS Regional offices will be included in the monitoring and coordination of HIV prevention programs.

AIDS - MEASURING GRANTEE PERFORMANCE

Question. What specific quantitative measures does CDC consider valuable in measuring the performance of cooperative agreement grantees?

Answer. State and local HIV Prevention Projects have been requested to gather baseline data on the knowledge, attitudes, beliefs, and behaviors (KABB) of various target populations. Using these data, projects are expected to develop anticipated outcome objectives which reflect changes in these baseline levels as the result of program activities. Follow-up KABB surveys, documenting changes over time, are an important source of quantitative information to assess the performance of cooperative agreement recipients. Other measures include changes in STD rates, data from counseling and testing sites, e.g., ability to provide counseling and testing services to people at risk including minorities, IV drug users and homosexual men, the number tested, the number returning for test results, persons seropositive, partner notification services provided, and partners seeking counseling and testing after referral.

Funded programs are expected to periodically submit a variety of data in specific formats following procedures and protocols previously established. Site visits are made to each area at least annually to assess whether procedures and protocols are being followed, to identify obstacles in implementing methods, and to collaborate with recipients in developing corrective solutions. Submitted data are reviewed for timeliness, completeness, and accuracy, and problems are promptly discussed and resolved with the recipient.

There are several quantitative measurements which are valuable in assessing the performance of school health HIV prevention cooperative agreement recipients. Information is provided on the number and percentage of schools within their jurisdictions that provide HIV education. Grantees also provide the number and percentages of students in each grade level (grades 7-12) who have received HIV education, and the number of class periods that are devoted to that educational activity. Information is also provided on the education and training of the persons providing HIV education, the types of materials used, and the primary setting of the HIV education programs. In addition, the grantees collect and report data on HIV-related student knowledge, beliefs, and behaviors. The collection of this student information is contingent upon receiving appropriate clearance at the State or local level. They also are requested to evaluate their efforts and to improve their programs based upon these evaluations. CDC provides technical assistance in all areas of data collection.

Question. How does CDC plan to use the uniform data it is now trying to collect to evaluate grantee performance?

Answer. CDC will begin to conduct on-site operational reviews of HIV prevention programs in the States and municipalities most heavily affected by the HIV epidemic. Information gained from these reviews, which will be collected according to a standardized protocol, and data from knowledge, attitudes, beliefs, and behavior

surveys, as well as, that from counseling, testing, and partner notification activities will be used to assess progress in State and local areas. This information will be used to establish a baseline upon which to assess future performance and to develop future technical assistance programs.

NHANES III

Question. What is the current status of NHANES III?

Answer. Field work for NHANES III began in October of 1988 and is currently on schedule. As of the first week in April, data collection has been completed at five locations in the Southwest and about 1850 sample persons have been examined. The examination response rate for the survey thus far is nearly 78 percent. By the end of the year, 14 sites will be completed. The survey is operating with a sample design expected to yield 30,000 examined persons over a six-year period.

INFANT MORTALITY RATE

Question. How does the U. S. infant mortality rate rank as compared to other nations?

Answer. When compared with other countries, the infant mortality rate for the United States for 1985 (10.6 deaths of infants under one year of age per 1,000 live births) ranked 22nd. This ranking is based on information compiled in Health United States 1988 from reports of the United Nations and individual countries.

Rankings are based on 1985 data for countries or geographic areas with at least 200,000 population and "complete" counts of live births and infant deaths as indicated in the United Nations Demographic Yearbook, 1985.

The country with the lowest rate was Japan (5.5), followed by Iceland (6.1) and Finland (6.3). In terms of infant deaths for only the white population of the U.S. (9.3), we would be tied with Singapore with a rank of 16th.

Despite a reduction in infant mortality for the U.S. during 1980 to 1985, the rank of the U.S. dropped from 19th to 22nd during this period. Also ranking 19th in 1980 were New Zealand and the Federal Republic of Germany.

EQUIPMENT - NCHS

Question. It is important that survey data to be as current as possible to evaluate and direct health programs. Does NCHS have the state-of-the art equipment necessary to ensure that data from their surveys are made available on a timely basis?

Answer. Automation, technology development, and timeliness have been high priorities in NCHS. Although more could be done, NCHS resources for technological development have increased significantly even through difficult budget years. NCHS has had a proud tradition of being a leader in the application of advances in statistical methodology and computer technology to its mission of providing

timely, accurate, and relevant health statistics to the nation. For example, NCHS has been considered a leading force in the development of Computer Assisted Telephone Interviewing techniques, now widely used in both public and private organization. NCHS is probably the first Federal agency to develop computer software for States to do their day-to-day work. The system, developed over a decade ago, helps States automate the medical coding on death certificates and remains an integral part of the national vital statistics system.

FULL TIME EQUIVALENTS

Question. As you know, we have tried to give you sufficient flexibility to provide the FTEs you need to effectively and efficiently manage your programs. Have you been given sufficient FTEs?

Answer. The FY 1990 President's budget for CDC includes 4,570 FTEs subject to staffing ceilings. This is an increase of 74 FTEs over FY 1989, and an increase of 154 FTEs over FY 1988 actual staffing levels. This level is expected to be further augmented by about another 654 FTEs exempt from employment ceilings, which are primarily public health advisors working with the States. This would bring the total CDC staffing level to about 5,244 FTEs for FY 1990. If this level should prove to be insufficient to conduct our planned programs, we would expect to discuss with the Assistant Secretary for Health the potential for FTE reallocations within the PHS.

Question. Why is there a decrease of 18 FTEs in your budget request?

Answer. Through continuing management improvements, such as implementation of automated travel and accounting systems and increased contracting for services, CDC will require 18 fewer FTEs in FY 1990 for those services.

REPAIRS AND IMPROVEMENTS BUDGET

Question. Your budget for repairs and improvements has remained below $2 million for several years. Is this level of funding sufficient to maintain your facilities?

Answer. With the $2 million requested in the FY 1990 President's budget, CDC will fund the highest priority maintenance and repair projects for its facilities, most of which are approaching 25 to 30 years of age.

RESEARCH EQUIPMENT

Question. What is the current state of your research equipment?

Answer. We are currently able to meet the requirements that have been established for CDC with the equipment we now have.

DIABETES

Question. States have told us that they have applied for funding of diabetes projects and were told that CDC had insufficient

funds to award their project. Is this true?

Answer. The 1989 appropriation provided $4.9 million for diabetes control demonstration projects, approximately the same level as in 1988. While it is true that not all project applicants have received funding, CDC has increased the number of States receiving cooperative agreements for diabetes programs from 20 in 1985 to 30 in 1988. CDC also places a priority on continuation funding for projects already underway and in the middle of their grant period; this limits the number of new awards provided each year.

Question. Are we doing all we can for our Nation's 6 million diabetics?

Answer. Currently, 29 States and one Territory are provided a total of $4.9 million to support diabetes control programs. The goal of these State-based programs is to reduce excess morbidity and mortality as well as costs from the preventable complications of diabetes.

Diabetes is one of the leading causes of death, morbidity, and excess mortality among minority populations. Thus it is one of the most important chronic diseases for public health programs to target. Although much more needs to be done, since mortality from diabetes has failed to decline during the 1980s, the CDC-funded State programs have begun to achieve the gains projected in several areas, such as prevention of blindness and reduction of adverse outcomes of pregnancy among women with diabetes. Some States that do not have CDC funding for their programs have been able to achieve third party coverage for outpatient diabetes education, a proven cost-effective service. In addition, outpatient education is beginning to be covered in other States using the methodologies developed in the CDC-funded State projects. The "Guide for Preventive Health Services for People with Diabetes" will become available in early 1990 and widely disseminated to public health programs and private practitioners. This guide should, through its effect on professional practice patterns, substantially increase the availability of comprehensive preventive care to patients with diabetes, by improving the quality of care offered to these patients.

Question. Congress has provided $2.4 million for translating research findings into health programs to reduce morbidity and mortality. Are these funds sufficient for the job you have been given?

Answer. Multiple projects on translating diabetes research findings into health programs to reduce morbidity and mortality were implemented in fiscal year 1988 and additional activities are being developed for implementation in 1989. These projects are both an expansion of past activities and the development of new ones. The process of translation is complex and includes design, testing, and evaluation of pilot intervention strategies.

CHRONIC FATIGUE SYNDROME

Question. Has any progress been made in defining and controlling chronic fatigue syndrome?

Answer. At this point, our current studies are too early in their development to be yielding any results that can be reliably interpreted. A contract for an experimental surveillance system has been awarded and should be initiated by the middle of August. This surveillance system will allow us to:

- Develop an effective prototype CFS surveillance and long-term follow-up system; we will attempt to develop and evaluate such a system, so that it could be expanded in the future to include other U.S. population areas, if so desired. A major current problem is that the diagnosis of CFS is both complicated and controversial; there are no pathognomonic laboratory tests and few objective abnormal clinical findings.

- Examine physician diagnostic procedures and related diagnoses in relationship to patients with chronic fatigue of unknown etiology.

- Provide objective estimates of the incidence and prevalence of CFS in selected populations over time.

- Identify patterns of symptoms and timing of their occurrence during CFS illness and recovery, including the sequence and timing of psychiatric symptoms in relationship to illness onset.

- Establish the nature and degree of neuropsychological problems in CFS and compare these observations with self-reported symptoms.

SPINA BIFIDA

Question. CDC recently published a paper showing that women who reported using multivitamins before pregnancy and into the early part of pregnancy have about one-half the rate of spina bifida infants as women who did not report using multivitamins. Since spina bifida is one to the most common and disabling birth defects, what additional research does CDC recommend in order to decide whether giving multivitamin supplements to women of reproductive age prevents spina bifida?

Answer. While NIH is conducting a randomized clinical trial in Egypt, of the use of vitamins to prevent the recurrence of spina bifida in women with a previously affected child, they are not studying the use of periconceptional vitamin supplementation to prevent the occurrence of spina bifida among women in the general population. Interest in conducting such a study has come from CDC. This has grown from CDC's extensive experience in the epidemiology of spina bifida and other birth defects and their role as the key Public Health Service agency for prevention activities.

Question. Why shouldn't we stop the research and begin treating all women of reproductive age right now?

Answer. The current evidence does not permit us unambiguously to conclude whether the apparent protective effect of multivitamins results directly from multivitamin use or from other characteristics of women who use vitamins. Until there is clear evidence that periconceptional supplementation with multivitamins prevents spina bifida, we should not supplement all women of reproductive age because there is a risk that such supplementation would precipitate a previously unrecognized and serious complication of supplementation. Some vitamins, in high doses, are believed to be harmful to fetuses. Until there is proven efficacy, we can not justify the risk or cost of wide spread supplementation.

Question. To what extent has CDC conducted research into spina bifida?

Answer. CDC has been involved in spina bifida research for many years. For over 20 years CDC has conducted surveillance for these and other birth defects nationally and in Atlanta. Additionally CDC has collaborated with States and other countries to develop surveillance capabilities. From the Atlanta surveillance have come several studies of spina bifida. One, in 1981, was based on maternal interviews studying whether multivitamins prevent spina bifida and anencephaly. In 1982, CDC worked closely with international colleagues to describe the causal association between valproic acid, an anticonvulsant, and spina bifida. These activities led to changes in the FDA's labelling of the drug. CDC reported in 1983 the geographical distribution of spina bifida in the United States and showed that there were increased rates in the East, especially Appalachia. CDC showed that during the 1970's, the survival of children with spina bifida substantially increased. In 1988, CDC published data from a case-control study suggesting that periconceptional multivitamin supplementation may reduce the incidence of spina bifida by 50%. Finally, CDC, along with several Institutes of NIH and the Spina Bifida Association of America, is planning a scientific meeting later this year to develop a long-term agenda for spina bifida research.

Question. Has CDC considered supporting research in other countries, such as China, where the incidence of the disease is high?

Answer. Yes we have. Through our international contacts we became aware that rates of spina bifida and anencephaly are very high in some regions of China. This was confirmed through WHO sponsored surveillance near Beijing, in which CDC has participated. For one year we have been looking into doing a randomized clinical trial of periconceptional multivitamin supplementation in China. Several factors make China an ideal place to conduct this trial. The rate of spina bifida is very high which will decrease the number of subjects needed to observe a statistically significant protective effect should one exist. In addition, the population is stable and there are no commercially available multivitamins in use to complicate the trial. Recruitment of women before they become pregnant would be easy since women register before marriage and the fertility rate in the first year of marriage is very high. Finally, we have established contacts with highly qualified collaborators in

China who are operating an excellent perinatal surveillance system in the area. The Chinese scientists and public health establishment are keenly interested in participating in a large scale clinical trial because spina bifida and anencephaly are the leading cause of infant mortality in the high rate areas of China. All of these facts lead us to be optimistic about the possibilities of doing a trial in China.

Question. What is your best estimate as to the number of children and adults that are surviving with this condition, and what is the best estimate as to the cost to our society?

Answer. Based on rates from CDC's Birth Defects Monitoring Program and the number of births from the National Center for Health Statistics, CDC estimates that from 1980 through 1987, approximately 13,600 infants born in the United States had spina bifida. An estimated 9800 of these children were alive in 1987. The monetary cost is difficult to measure. Dr. Joseph Lipscomb from Duke University has made some estimates in 1985 dollars. The expected cost for medical and surgical care for one person with spina bifida from birth through 18 years of age approaches $100,000. He estimated the lifetime average costs to be almost $250,000 per case of severe spina bifida when the larger societal costs including medical and surgical care, long-term and foster care, loss of parental income, disability, education, and productivity are included. We believe that in the United States $200 million a year is spent for medical and surgical care alone for all persons with spina bifida.

CHILDHOOD LEAD POISONING

Question. What is the nature and extent of the childhood lead poisoning problem in the United States?

Answer. Childhood lead poisoning is an entirely preventable disease. Yet, a recent report to Congress from the Department of Health and Human Services estimated that between three and four million children have lead levels high enough to affect health. A disproportionate number of these children are poor, inner-city minority children. The effects of elevated lead levels in children include disturbances of blood production, decreased intelligence, slowed development, and behavioral disturbances. Many of these effects will persist long after exposure has ended, perhaps for the lifetimes of the affected children.

Question. What experience and expertise does CDC have in childhood lead poisoning prevention?

Answer. CDC has had an active lead poisoning prevention program since 1973. Working with expert committees, CDC developed the lead screening guidelines used by most pediatricians and screening programs. These guidelines are updated every 3-4 years. CDC has conducted many critical epidemiologic studies of lead exposure and poisoning. We continue to work with state and local authorities in lead poisoning prevention programs and serve as a reference laboratory for blood lead measurements in proficiency programs and national surveys.

Question. How much progress can we realistically expect to make in reducing and preventing childhood lead poisoning in the next decade?

Answer. Childhood lead poisoning is an entirely preventable disease. Removing lead from gasoline has taken over a decade; preventing exposure in old housing will be even more difficult. Nevertheless, we hope that a concerted, nation-wide effort will eliminate this environmental disease within the next 10-20 years.

TUBERCULOSIS ELEMINATION

Question. We understand that a federal strategic plan has been developed to eliminate tuberculosis from the U.S. by the year 2010.

What is the cost to initiate and support such an endeavor?

Answer. "A Strategic Plan for the Elimination of Tuberculosis in the United States" has been developed by the Department's Advisory Committee for Elimination of Tuberculosis (ACET). The plan calls for the elimination of TB (i.e., an incidence of <1 case per million population) from the U.S. by the year 2010. The plan provides a roadmap to guide this effort, which will require a committed partnership between the Federal government, State and local governments, the private sector, voluntary organizations, and patient advocacy groups.

The plan has three action steps:

Step 1 More effective use of existing prevention and control methods, especially in high-risk populations;

Step 2 Development and evaluation of new technologies for treatment, diagnosis, and prevention; and

Step 3 Rapid assessment and transfer of newly developed technologies into clinical and public health practice. CDC estimates that, currently, at least one-third of the cases among minorities and one-half of the cases among immigrants and refugees are potentially preventable. Recommended priorities for prevention actions include: 1) identifying and screening high risk population groups through tuberculin skin tests; and 2) increasing the availability of adequate and appropriate chemotherapy treatment for those infected with the disease and chemoprophylaxis to those who are infected with the tubercle bacillus to prevent them from developing the disease.

The plan calls for further research targeted toward developing more rapid and effective methods of diagnosis, treatment, and prevention. Many of the current diagnostic techniques have been used for over 50 years, and some of the best drugs are nearly 40 years old. The only vaccine is nearly 70 years old and is not optimally effective.

Finally, the plan points out that Federal, State and local health agencies; professional societies; schools of medicine, nursing, and public health; and minority advocacy groups all have a role in assessing new technologies and ensuring that these are put into clinical and public health practice in a timely fashion. These groups also share responsiblities for educating health care providers and high risk groups about the manifestations, methods of diagnosis, treatment, and prevention of TB. The plan recommends the use of national, regional, and State educational conferences for health care providers and the establishment of State and local advisory committees to review progress towards TB elimination in their jurisdictions.

At the Federal health level, the plan expects that CDC, the Food and Drug Administration (FDA), and the National Institute of Allergy and Infectious Diseases (NIAID) will continue to work together to carry out TB elimination efforts. While the ACET's Strategic Plan does not specify potential funding levels to implement its recommendation, the professional judgement of CDC program staff estimate that FDA and NIAID would together need about an average of $5.7 million a year to identify and develop new treatment and diagnostic methods. Fully implementing other TB elimination activities through CDC could require up to $36 million a year for the first five years, after which costs would decrease as fewer cases were reported.

The FY 1990 budget proposes to fold the $6.6 million of current Federal categorical support for TB control and prevention activities into the Preventive Health Services Block Grant. The block grant is an important source of Federal support for State and local health department activities. It is designed to give States maximum flexibility in using Federal funds to address problems which they identify as high priorities. Our strategy for eliminating TB has been shared and discussed with the States, and CDC intends to continue to work with the States to carry out that plan under any funding mechanism.

TUBERCULOSIS - BLOCK GRANT

Question. The Administration has proposed that federal funding of tuberculosis control activities be folded into the Preventive Health Services Block Grant.

How will placing TB grants in the block grant affect your ability to provide and maintain TB preventive and control activities?

Answer. The block grant is an important source of Federal support for health department activities. It is designed to give States maximum flexibility in using Federal funds to address problems which they identify as high priorities. We have previously described our strategy for elimination of Tuberculosis and assure you that we would continue to work with the States to carry out that plan.

CLINICAL LABORATORY TESTING

Question . What is CDC doing to address the problem of laboratory training?

Answer. The Centers for Disease Control and the Association of State and Territorial Public Health Laboratory Directors have implemented a National Laboratory Training Network, a unique laboratory training delivery system that is State operated and supported by CDC on a national scale. The Network is composed of seven Area Laboratory Training Alliances that represent a coalition formed among State public health agencies, academic institutions, private sector and professional organizations, and commercial companies involved in laboratory practice, within a defined geographic area. The training alliances are strategically located throughout the United States with area resource offices in Boston, Massachusetts; Chicago, Illinois; Nashville, Tennessee; Exton, Pennsylvania; New Orleans, Louisiana; Denver, Colorado; and Berkeley, California. Each area resource office, staffed by an area resource director and a CDC training advisor, will serve as the operational focus to: establish open and frequent communication between alliance members and other participants of the Network; identify the need for laboratory training in a particular discipline; develop and deliver laboratory training activities to meet identified needs; and evaluate the impact of training on laboratory performance. The uniqueness of the National Laboratory Training Network is that it provides a forum for <u>all</u> entities dedicated to serving, supplying, and improving the Nation's laboratory system. The Network will eliminate duplicative effort in developing laboratory training activities by providing a current inventory of available Federal, State, local, and private sector training resources.

The Network will provide cost effective methods to meet the training needs of a large target audience of laboratorians, provide for the timely transfer of new testing technology, promote the standardization of laboratory training, monitor training activities with a national focus, and assure that laboratory training meets the identified need to improve the efficiency and effectiveness of the Nation's laboratory system.

Question. Clinical Laboratory testing is a multi-billion dollar business. What is the quality of clinical laboratory testing in this country?

Answer. In general, we define "quality" as those requirements for access, reliability, utility, timeliness, and cost-effectiveness in the laboratory testing process that must be met in order to satisfy the needs of the patient. Presently, there are no absolute standards for quality in most laboratory testing situations; the requirements are set through practice.

Most empirical evidence suggests that laboratory performance is better today than at any previous time in the history of medical testing. Since the enactment of the Medicare law and the Clinical Laboratories Improvement Act of 1967, there have been substantial improvements in the performance of the Nation's clinical laboratories. Some demonstrated measures of improvement include: increased utility and reliability of test reagents and systems; decreased turn-around-time for test results; and overall cost-effectiveness of testing methodologies. These improvements can be attributed to advances in technology, regulatory activities, and educational and training programs by professional societies, private industry, and government groups.

Despite the improvements in the quality of laboratory testing that have taken place, we don't have adequate data on a large scale which define the individual determinants of testing quality. Epidemiological and laboratory studies are necessary to identify and to evaluate the factors which influence the quality of clinical laboratory testing. Some of the necessary studies are called for in the Clinical Laboratory Improvement Amendments of 1988. A significant part of the research effort should be directed at the issue of how to measure, adequately and appropriately, the quality of laboratory work as it applies to community and individual health and treatment, as well as disease prevention strategies.

Most independent and hospital laboratories are using established quality assurance procedures and participating in proficiency testing programs, and many are approved by regulatory or voluntary professional organizations. While these activities can improve the analytic quality of testing, they do not directly address the problems in collecting and preparing a specimen before it is analyzed and interpreting and using the results of the analysis. The practice of laboratory medicine is not perfect and must be constantly monitored to detect deficiencies. In addition, studies are needed to determine not "how well laboratory analyses are done," but "how well the total process of testing meets clinical and public health needs."

Question. What is CDC doing to define where the real problems are in clinical laboratory testing and how can we correct these problems?

Answer. CDC has long supported the concept of testing as a process which extends beyond the actual analytic process. Our Model Performance Evaluation Program not only provides laboratories performing HIV testing with an opportunity to evaluate their performance on the basis of a quarterly panel of unknown specimens,

it also collects data on the pre-analytic and post-analytic aspects of HIV testing. Through study of this data, and in cooperation with the University of San Diego School of Public Health, we are attempting to gain a more comprehensive understanding of how various aspects of the total testing process impact a recognized public health goal, namely, the prevention of HIV infection through accurate, high quality HIV testing.

The Centers for Disease Control has also conducted pilot research into the impact of laboratory error surveillance systems on health outcome in a private hospital setting. Analysis of these pilot data have convinced us of the need to develop and implement a larger scale, prospective study to more fully understand the impact that laboratory testing can have on health outcomes. The studies called for in the CLIA '88 legislation also recognize the importance of improving our understanding of the total testing process through scientifically designed research. These studies have not been initiated.

The Institute of Critical Issues in Health Laboratory Practice is an ongoing activity, which serves as a forum for clinicians, laboratorians, and manufacturers to come together to identify problems in laboratory testing, and discuss possible solutions to these problems. The most recent Institute was held in April 1989 and served as a focus for the discussion of improving the quality of health management through clinician and laboratorian teamwork.

LEAD POISONING

Question. Over 12 million children each year are exposed to some form of lead poisoning, causing learning disabilities and other health problems. How is CDC addressing the problem of lead poisoning?

Answer. CDC administered the childhood lead poisoning prevention block program until 1982 when these funds were folded into the Maternal and Child Health (MCH) Block Grant. In addition, working with expert committees, CDC developed and updated the lead screening guidelines used by most pediatricians and screening programs. CDC has also conducted many critical epidemiologic studies of lead exposure and poisoning. We continue to work with State and local authorities in lead poisoning prevention programs and serve as a reference laboratory for blood lead and erythrocyte protoporphyrin measurements in proficiency programs and national survey.

Question. Does CDC have any plans to work with the Department of Housing and Urban Development on lead removal during HUD's remodeling of these old housing projects?

Answer. A recent report to Congress for the Department of Health and Human Services (Agency for Toxic Substances and Disease Registry) estimated that over 12 million children younger than 7 years old live in housing with leaded paint, and at least 1.2 million of these are estimated to have blood lead levels above 15 ug/dl, levels believed to be associated with decreased intelligence, developmental delays, and behavioral problems. Although screening children for lead poisoning is an important part of the public

health campaign to eleminate childhood lead poisoning, elimination of the environmental sources of undue lead exposure is essential for success.

CDC remains available to work with the Department of Housing and Urban Development (HUD) on its lead-related activities and encourages HUD to incorporate HUD-related lead paint abatement activities into effective public health programs.

IMMUNIZATION FUNDING

Question. The FY 1990 budget request reduces funding for immunization by $3.7 million by eliminating funding for the vaccine stockpile, and basically, retaining level funding for the remainder of the immunization program. Your justification states that an estimated 250,000 new hepatitis B infections occur in the U.S. each year, requiring 50,000 hospitalizations, resulting in 4,000 deaths per year.

Given these facts, why hasn't funding been included in the FY 1990 budget for the highly effective hepatitis B vaccine?

Answer. The highest priority for the immunization program has been to maintain the current level of support for immunization programs against polio, measles, mumps, rubella, Haemophilus influenzae type B (Hib), diphtheria, pertussis, and tetanus. Our 1990 budget request provides resources to purchase the same number of doses of polio, MMR, Hib, and DTP vaccine as were purchased in 1988 and 1989.

Question. CDC announced its goal for eliminating measles by 1982. Obviously, that goal was not reached. I assume that you have a strategy for eradicating measles. How much is in the FY 1990 budget to implement those strategies beyond the purchase of vaccine?

Answer. In January 1989, the Immunization Practices Advisory Committee (ACIP) issued new recommendations to assist in the elimination of measles and the control of measles outbreaks. Since these recommendations were issued after the formulation of the 1990 budget request, no additional funds were requested in the 1990 budget to implement these new recommendations.

OCCUPATIONAL SAFETY AND HEALTH

Question. Dr. Dowdle, the FY 1990 budget calls for about a 35 percent reduction in funding for occupational safety and health. Did you propose this funding cut?

Answer. This proposal for a reduction in the NIOSH budget originated at the Office of Management and Budget. Although the FY 1990 budget originally proposed this reduction, an amendment to restore this reduction was forwarded by the President to the Congress on May 18, 1989.

Question. What was your request for funding for occupational safety and health?

Answer. Request to PHS for FY 1990 funding for the National Institute for Occupational Safety and Health was in the amount of $102,334,000.

Question. Did you appeal this reduction?

Answer. Yes, this reduction was included in the Department's appeal of the initial OMB allowance for FY 1990.

NIOSH TRAINING

Question. What are the current training needs, in numbers, in the several disciplines supported by the NIOSH training program?

Answer. It is not possible to give a defensible estimate of these numbers. However, several estimates give some indication of the situation. The Institute of Medicine has estimated (1988 Report "Role of the Primary Care Physicians in Occupational and Environmental Medicine") that there are around 1,000 specialists in occupational medicine in this country, which is about one for every 100,000 workers. The Industrial Hygiene Association estimates there are 10-12,000 industrial hygienists in the country (there are 22 million workers in manufacturing and mining).

Question. Is there currently any training emphasis in training physicians, industrial hygienists, nurses and safety specialists to deal with the epidemic of agricultural injuries and disease?

Answer. There is no training effort on our part targeted specifically to addressing agricultural injuries and diseases. The ERC program has trained 9,075 full-time students, 19,283 part-time students, and 128,811 students in continuing education. Certainly some of the physicians, industrial hygienists, safety specialists, and nurses among these ERC students are working in this area, but we have no estimate of their number. There are three States conducting special efforts to deal with problems in agriculture: New York, Iowa, and Kentucky, but we are not aware of a training component to these efforts.

EDUCATIONAL RESOURCE CENTERS

Question. How can the current Educational Resource Center program be strengthened or enhanced to assure consistent quality and regional coverage across the United States?

Answer. The existing 14 ERCs will continue their programs in graduate level education, continuing education, outreach and research training. Periodic peer review and program monitoring site visits will assure the best programs receive priority for funding and guarantee their quality output. All programs will be reviewed annually and will receive summary statement reports with specific directives for continually improving their performance.

To provide optimal regional coverage, the ERCs are requested to conduct periodic needs assessments to determine the demand for new professionals entering the field and the need for continuing education programs for current practitioners in emerging areas . ERCs with three core disciplines are encouraged to add a fourth. The

four core disciplines are occupational medicine, industrial hygiene, occupational safety and occupational health nursing. All ERCs are asked to develop collaborative relationships with other disciplines (i.e., schools of business, engineering, and medicine) within their own university structure as well as with other colleges and universities in their region.

LEAD POISONING

Question. Each year thousands of children under six years of age are hospitalized for treatment of lead poisoning, and tens of thousands are exposed to lead to a degree that may affect their behavior or impair their intellectual development. Much of this exposure occurs in older buildings which have the highest lead concentration in its paint. I am advised that 172,500 children in Philadelphia and 71,300 children in Pittsburgh between the ages of 0.5 and 5 live in pre-1950 housing.

In 1988, Congress passed the Lead Poisoning Prevention Act authorizing a Program to screen infants and children for elevated lead levels; assure medical referral and environmental intervention; and provide education about childhood lead poisoning. This program is authorized at $22 million.

Was any consideration given to funding this program in FY1990?

Answer. There was no discussion of funding the programs of the Lead Poisoning Prevention Act for 1990. First of all, this law was enacted after decisions on the 1990 President's budget had been concluded. Second, States are able to use funds from the Maternal and Child Health (MCH) Block grant to provide lead screening and education services. For 1990, $554.3 million, the same level as 1989 and a record high, is being requested in the MCH block grant. CDC would encourage the States to direct such resources to lead poisoning prevention.

Question. How would the funds be allocated to the States if funding were provided for this program?

Answer. CDC would place a notice in the Federal Register describing the grant program and requirements for applying for grants, grant applications would be reviewed and money awarded based on how well applicants fulfill the criteria described in the legislation. A priority would be given to applications for programs which will serve areas with a high incidence of elevated blood lead levels in children.

Question. How effective do you believe this program would be in reducing the incidence of hospitalization for treatment of lead poisoning?

Answer. Lead poisoning is often a silent disease. Effects of lead poisoning like decreased intelligence, slowed development, and behavioral problems are likely to be blamed on other factors unless lead poisoning is looked for specifically. At least in the short term, it is likely that enhanced screening programs would result in increased hospitalizations for treatment of lead poisoned children who would otherwise go undetected.

NATIONAL CENTER FOR HEALTH STATISTICS

Question. On March 28, 1989, I received a letter from the Director of the Population Studies Center at the University of Pennsylvania. Director Preston indicated that the National Center for Health Statistics may not be able to continue to gather data on marriage and divorce due to budget constraints. Will the Center continue to collect this data in FY90?

Answer. The FY 1990 budget request for NCHS does not provide for the continued support of the marriage and divorce components of the National Vital Statistics System, and NCHS will discontinue funding to the States for the collection of these statistics. Although many States will continue to produce marriage and divorce statistics for their own use, NCHS will no longer compile detailed marriage and divorce statistics at the national level through this mechanism. With the $5.1 million in additional total resources proposed to be made available in 1990, NCHS had determined that the data needs of the national public health and health care system would be better served by placing a higher priority in 1990 on using resources to follow through on necessary modifications and improvements to the National Health Care Surveys than to continue support for the collection of marriage and divorce data in the current manner.

Question. How much will it cost to insure that this data will be collected?

Answer. It would cost approximately $676,000 to continue to fund the States participating in the marriage and divorce component of the Vital Statistics Cooperative Program. However, no offsets have been identified to accommodate program increases beyond the priorities of the 1990 President's budget.

Question. What provisions, if any are being made to ensure continuation of this program?

Answer. We recognize that marital status is an important aspect of health, and are cognizant of our responsibility to continue to provide data in this area. Through continuing surveys such as the National Health Interview Survey and the National Health and Nutrition Examination Survey, we obtain data on marital status to compare to other health status measures, and we are able to study marital in connection with our analysis of birth and death. To augment these systems in the areas of family formation and dissolution, sexual behavior and attitudes, child rearing, and health practices, we conduct several special studies such as the National Maternal and Infant Health Survey and the National Survey of Family Growth. Finally, we will be exploring ways in which we can obtain summary data from marriage and divorce records from the States where data is available.

AIDS FAMILY OF SURVEYS

Question. The Administration requests continuation of funding for the "family of surveys" regarding the prevalence of HIV infection in communities around the country. What is the value of these surveys?

Answer. The "Family of Surveys" provides to health departments in States and cities around the country ways to assess and monitor the levels and trends of HIV infection in the various subpopulations of concern in their areas. These subpopulations include, among others, sexually active heterosexual men and women, homosexual and bisexual men, intravenous drug users, civilian applicants for military service, Job Corps applicants, blood donors, and childbearing women. In addition, some States have requested and received support from CDC to develop HIV surveys in prisoners and in homeless populations.

These survey activities serve as a public health management tool. The HIV/AIDS epidemic is extremely variable in terms of: geographic distribution; impact by age, sex, and race; and behavioral risk. It is important for State and local health departments to be able to assess and monitor segments of their population at greatest current risk so as to be able to target and evaluate prevention efforts. Important questions include whether heterosexual transmission is occurring locally, whether local intravenous drug users are becoming infected, and whether and where women of childbearing age are infected. Most importantly, health departments must assess whether, when, and where the situation is becoming worse.

The value of the surveys to public health practice is best judged by the enthusiasm of health officials around the country. The first year of activities included 30 major cities in 24 States and territories. Based on requests from the States, nine additional major cities and a total of 44 States now are included in the standardized approach to HIV assessment and monitoring through surveys and studies. In 1990, we expect to support approximately six additional cities for a total of 45, and to fund selected HIV surveys and studies in the remaining states for a total of 50.

Question. What initial data has been gathered?

Answer. The family of surveys, comprised initially of a limited number of serologic studies, surveys, and analyses of HIV seroprevalence data from sentinel hospitals, blood donors, and civilian applicants for military service, has developed into a broad mix of nationally conducted population and clinic-based serologic surveys and studies that are now beginning to provide critically needed data. These focused surveys and studies, each highlighting a different element of the HIV/AIDS epidemic, are continuous or recurring at annual intervals to permit monitoring of trends as well as levels of HIV infection in the various groups at risk.

Implementation of the family of surveys represented a new kind of national surveillance effort in response to the HIV/AIDS epidemic. The surveys have been implemented incrementally, and data will become available as study sample sizes are reached (1,500 eligible specimens from STD, 1,000 for women's health, 600 for IV drug abuse, and all available specimens from tuberculosis clinics). Because of differences in the availability of eligible specimens from site to site, some areas will require longer to complete the individual surveys than others. As of April 1, 1989, preliminary data from 22 clinics and neonatal data from 9 areas had been received at CDC. When complete data are received, they will be

assembled in various charts, graphs, tables, and texts for dissemination (in full collaboration with cooperating health departments).

Over time, as trends of infection in the various groups being surveyed become clear, it will be possible to know more precisely where prevention efforts should be directed and how to guide the public health response.

CDC has confirmed the enormous diversity of impact of HIV infection by geographic area, urban vs. rural residence, age, gender, and race/ethnicity, and by behavioral patterns. CDC has also learned that there is considerable enthusiasm in state and local health departments for developing data to assess and monitor the patterns of HIV infection in their areas of responsibility to aid in targeting and evaluating prevention programs. CDC has expanded its efforts from the initial 30 cities in 24 States and territories involved in the family of surveys in 1988 to include 39 cities and 44 states and territories involved in the family of surveys and neonatal HIV surveillance. CDC has also learned that simply conducting the surveys has had a major impact by showing health department and clinic personnel that HIV really occurs in the populations they serve. This has made the epidemic more "real" and immediate to the public health and clinical communities in the areas involved in the family of surveys.

Question. What implications do these data have on the targeting of prevention efforts by the CDC or planning regarding care and services by other PHS agencies?

Answer. HIV prevention activities are performed by local health departments, clinical care-providers, and community organizations which actually have access to the groups and individuals at risk. CDC provides technical guidance, training, resources and support for the prevention activities. Data from the HIV surveys and studies, as well as from AIDS case surveillance and knowledge-attitude-behavior assessments, assist CDC and State and local health departments in determining priorities for allocating prevention resources by identifying those groups that are locally at highest current risk of infection. (The relative current importance of the various modes of transmission and the groups at highest risk vary enormously from area to area.) Targeting of prevention efforts is, ultimately, a local decision. In addition, HIV seroprevalence data are useful to other PHS agencies. For example, HIV seropositivity data are critical for planning the delivery of health care services which will be required to meet the needs of AIDS patients diagnosed in the future.

Question. What is the relationship between the family of surveys and the pilot testing of the household seroprevalence study?

Answer. Currently, there are no accurate national data on the prevalence of HIV in the United States, although estimates have been constructed by CDC using indirect methods. The family of surveys and the National Household Seroprevalence Survey (NHSS) are designed to provide more direct estimates of the HIV infection. These two data sources also have the potential for providing information about the spread of the HIV over time. The family of surveys is a

collection of independent data systems which survey a number of special subgroups of the population. The family of surveys is establishment-based (health facilities) and includes drug treatment centers, clinics for sexually transmitted diseases (STD's), tuberculosis clinics, clinics serving women of reproductive age, patients of general hospitals, and infants born in hospitals. Except for newborns, the populations using these facilities are difficult to define, and large segments of the U.S. population are not covered by the family of surveys. The family of surveys will provide HIV estimates for the selected facilities which will be extremely valuable for monitoring HIV infections over time at the local level. Broader statistical inferences to subgroups in the United States population will be difficult.

The NHSS is a population-based survey which covers the entire civilian non-institutionalized household population in the United States. Participation in the NHSS is strictly voluntary. The primary drawback of the NHSS is the potential for a serious underestimate of the HIV infection. If persons most likely to have the HIV infection participate at a different rate than persons at low risk to the infection, then an accurate estimate of the HIV infection can not be obtained This is an extremely difficult task and is the primary focus of the Dallas pretest.

The two data sources described above are being designed to complement and cross-validate one another. Questions asked in the NHSS could be used to define populations that are similar to the family of survey populations. A comparison of the HIV estimates for these populations will provide valuable information about the strengths and weaknesses of both types of data systems. Both of the data systems will also provide useful information for verifying the estimates and assumptions previously used by CDC to indirectly estimate the HIV prevalence.

A comprehensive information system must be designed to monitor epidemics with etiologies similar to AIDS. Both the National Vital Statistics System and the National Notifiable Disease Reporting System are quite adequate for detecting and monitoring the spread of infectious diseases that have short incubation periods and are easily diagnosed by physicians. The HIV infection associated with AIDS, however, cannot be adequately monitored by these traditional systems. We must also be able to measure and monitor the major risk factors associated with diseases such as AIDS. The family of surveys and the NHSS represent possible components of such a system.

Question. I understand a pilot survey has been completed in Pittsburgh. What is the outcome of this survey? Are there any plans to expand the scope of the study?

Answer. Considering the volatile social climate surrounding AIDS/HIV and the problems inherent in a general population survey of a phenomenon thought to be at very low prevalence, plans for the household HIV seroprevalence survey called for a feasibility study before any attempt to field a national survey. That study was begun with a pilot study in Allegheny County (Pittsburgh) where a three week field test took place in January 1989. The objectives of that study were limited to determining whether a household survey of HIV infection was logistically possible and whether it would be accepted

by a community. A very favorable climate throughout the Pittsburgh area was developed with the strong support of the Allegheny County Health Department and the assistance of a broad-based community advisory committee. There was a good response from the approximately 350 households in the sample. About 82 percent of the identified eligible adult sample chose to participate by giving a blood specimen and completing a risk questionnaire. The survey field procedures were found to be essentially sound, and the response rate compares very favorably with that of similar health surveys. However, it is still crucial to get better estimates of the possible impact of nonresponse biases. Preparations are underway for a second field test in Dallas County, Texas where the Pittsburgh model of obtaining health department and broad community support is being followed. The goals for this study are far more numerous and complex than those of the first. Foremost among these is the development of a sampling plan and survey methods that will produce a seroprevalence estimate for the Dallas area, and the implementation of a number of procedures that will provide a means to assess the quality of data collected. The survey of approximately 2,500 is currently scheduled to begin in July 1989.

The initial goals of obtaining HIV seroprevalence estimates for the U.S. population have not changed. The two feasibility studies have been progressively expanded in an attempt to provide adequate information to decide on implementation of the national survey. One could conjecture that, if a definitive conclusion cannot be reached after the Dallas study, some further "feasibility" work might be appropriately recommended. If a national survey is successfully completed, the data would establish a baseline for the U.S. population. Future similar surveys could then be used to monitor trends in the prevalence of HIV infection.

AIDS MINORITY PROJECTS

Question. Of the $379,152,000 appropriated in FY 89 to the Centers for Disease Control for AIDS Education and Prevention, just under $30 million was specifically targeted for minority projects. How have these funds been used?

Answer. In an effort to address the need for education and intervention programs to prevent HIV infection in minority populations, we implemented a National and Regional Grant Program for Minority Organizations and awarded 33 grants. We developed a cooperative agreement to directly support 75 minority and other community based organizations (CBOs) in 27 metropolitan statistical areas with the most HIV infections and AIDS cases. More than half of the funds will be awarded to CBOs which represent and serve minorities. We also implemented a program to support initiatives in 53 State and local health agencies to prevent HIV in minorities; more than 345 organizations received support through this funding mechanism. We continued to provide support and technical assistance to the U.S. Conference of Mayors which, in turn, supplied start-up funding and technical assistance to 37 minority community-based organizations. In August 1988, CDC co-hosted the second National AIDS Conference on the Prevention of HIV Infection and AIDS in Ethnic and Racial Minorities.

In addition to those efforts which are specifically directed to minority populations, the CDC conducts a multitude of HIV prevention activities which also benefit minorities. For example, Perinatal AIDS Prevention Projects, TB/HIV Control Projects, Health Education/Risk Reduction and Counseling, Testing and Partner Notification Programs address high-risk populations which include minorities. Also information/education messages directed to the public have minority components which are designed by minority advertising firms through subcontracts.

Question. What is the total funding for minority prevention activities?

Answer. The FY 1989 amount for minority prevention activities is $30,041,000 and the FY 1990 budget request is $47,240,000.

Question. How does this spending break down among grants to national organizations? Community-based organization? Programs funded through States and cities to be targeted for minorities?

Answer. The following table provides a funding breakdown of CDC HIV prevention activities directed to minority populations:

	FY 1989	FY 1990
National Minority Activities	7,888,000	8,072,000
State and Local Activities	16,763,000	17,153,000
Community Based Activities	5,390,000	9,515,000
Other Activities	0	12,500,000
TOTAL	$30,041,000	$47,240,000

Question. In funding national or community-based minority organizations, what assurances are being obtained that these organizations have experience working with and reaching those subpopulations within the minority community at risk to HIV?

Answer. Program announcement number 908, titled "Cooperative Agreements for Minority and Other Community-Based HIV Prevention Projects," which advertised the availability of funds, was explicit in its requirement that minority organizations provide assurances in the application that they have experience working with the communities they represent which are at high risk of HIV infection. Each applicant was required to submit the following:

- An organizational history, including a description of previous HIV prevention education and outreach activities, and general service and education programs provided in the past.
- An organizational structure, the interests and constituencies it represents, and its demonstrated and/or predicted ability to implement outreach and education programs to reduce the spread of HIV.
- A description of its commitment and ability to work with a variety of organizations and governmental programs, including those providing HIV prevention services, and to

coordinate program development with existing governmental and private educational efforts, and the degree to which the proposed program complements, rather than competes with, State and local health department efforts.

- o A description of its capacity to provide sensitive and appropriate education and outreach which responds effectively to the cultural, environmental, social, and/or multilingual character of the target populations, including documenting any history of such outreach or education by including previously used educational materials, program descriptions, etc.

AIDS COMMUNITY-BASED ORGANIZATIONS

Question. How many new and how many continuing grants will be permitted with the FY 90 request, compared with FY 89, for community-based organizations and for minority organizations?

Answer. It is estimated that CDC will be able to provide direct funding to approximately 75 community-based organizations (CBOs) in fiscal year 1989; approximately 55 of these organizations will be representing or serving minorities. In fiscal year 1990, CDC estimates that it will continue providing support to the 75 CBOs and will be able to fund approximately 25 additional CBOs; approximately 15 of these organizations will represent or serve minorities.

In addition, CDC estimates that, in fiscal year 1990, more than 500 CBOs, serving or representing minorities, will be funded through cooperative agreements with State and local health departments and with the U.S. Conference of Mayors.

Question. What are the geographic/demographic criteria for determining eligibility for federal grants to community-based organizations?

Answer. Eligible applicants for direct funding under the "Cooperative Agreements for Minority and Other Community-Based Human Immunodeficiency Virus (HIV) Prevention Projects" are nonprofit, community-based organizations (CBOs), located in the Metropolitan Statistical Areas most heavily affected by the HIV epidemic. These areas are defined by the cumulative number of AIDS cases reported to CDC and entered into the CDC database as of December 1, 1988. To qualify as a minority CBO, an organization must demonstrate that it represents and serves minority persons, and has a governing body which is composed of more than 50 percent racial and/or ethnic minority group members (i.e. Asians, Blacks, Latinos/Hispanics, Native Americans, and Pacific Islanders).

Question. Will community-based organizations from low-incidence communities have access to direct federal assistance for their prevention programs?

Answer. Congress directed CDC to provide funds directly to community-based organizations (CBOs) in the metropolitan areas having the greatest number of AIDS cases. Consequently, CBOs from low-incidence communities will not, in 1990, have access to direct Federal assistance from CDC for their prevention programs. However,

they will be able to compete for prevention funds which will be awarded by CDC to States, localities, and Territories through the AIDS/HIV Surveillance/Prevention Cooperative Agreements and from funds awarded through the U.S. Conference of Mayors.

INTRAVENOUS DRUG USERS

Question. Is the CDC now the lead agency in prevention programs for Intravenous Drug Users (IVDU) prevention?

Answer. CDC and NIDA both have a role with respect to drug abuse-related HIV infection.

CDC currently supports the following activities to prevent the spread of HIV infection among IV drug users:

- HIV counseling and testing (C/T) programs in drug treatment centers provide services to IV drug users (IVDUs) and their sexual partners. In FY 1988, approximately $15 million was spent on Counseling and testing services in drug treatment programs; in FY 1989, approximately $20 million has been budgeted. In addition, Counseling and testing programs in public health clinics (STD, womens health, and TB clinics, etc.) and alternate test sites provide Counseling and testing services to IVDUs who seek services at these locations.

- CDC finances community (including "street" outreach) activities, often conducted by ex-addicts who provide education and risk reduction messages to IV drug users and their sexual partners. These programs are supported through a variety of mechanisms, including the health education/risk reduction component of cooperative agreements to State and local health departments and through support of community-based organizations (CBOs) - both the United States Conference of Mayors and the upcoming direct funding of CBOs. The support of CBOs also aims to change community norms about drug use, needle-sharing, and other high-risk behaviors.

- CDC supports nine perinatal HIV prevention demonstration projects in seven locations which target women at high risk, particularly women IV drug users and women who are this sex partners. These projects provide educational programs to reduce drug use and other risky behavior, and increase use of contraception. One of the HIV community demonstration projects is examining how behavior can be changed among IV drug users. In fiscal year 1990, efforts will be expanded to approximately 20 areas having the highest potential for preventing HIV infection in children.

- CDC has developed a model joint plan that can be used by State and local health departments and State drug abuse agencies in the development of comprehensive HIV/STD prevention programs in drug treatment centers, which include voluntary HIV antibody testing, pre- and post-test counseling, follow-up services for HIV seropositives, TB screening, follow-up contraception counseling, and partner notification. CDC has requested that health departments

include such joint plans in their 1989 budget requests for cooperative agreement funds.

- To facilitate implementation of the above listed program activities, CDC has provided increased technical assistance and training to State health departments.

- CDC also supports national, State, and local public information programs which have appropriate IV drug user-related HIV prevention messages.

Question. If so, how will the CDC be assuring that it takes advantage of the experience NIDA has had working with IVDUs to assure a successful program?

Answer. CDC and the National Institute on Drug Abuse (NIDA) share project-related HIV prevention information on an ongoing basis and occasionally conduct joint site visits. CDC also provides copies of appropriate cooperative agreement applications to NIDA for review and comment. In fiscal year 1989, CDC provided NIDA with copies of HIV Prevention and Surveillance cooperative agreement applications from the 24 jurisdictions with the highest number of reported AIDS cases.

At the State and local level, CDC has requested that cooperative agreement funding recipients collaborate with drug abuse agencies in developing plans to address HIV prevention among IV drug users in drug treatment centers.

Question. What percentage of the CDC's prevention funding is targeted for IVDUs?

Answer. In fiscal year 1988, $15 million in HIV prevention funds was targeted to IV drug users receiving counseling, testing, and partner notification services in drug treatment centers. Currently, $20 million is available and $25 million has been requested for fiscal year 1990, representing approximately eight percent of CDC's total HIV Prevention budget. IVDUs also receive similar services through STD and TB clinics, family planning centers, and women's health services. In addition to the funds exclusively targeted to IVDUs, CDC supports a number of program efforts which also address HIV prevention in that population. For example, State and local HIV Prevention and Surveillance Programs and HIV School Health Education Programs, Community Demonstration Projects, and Perinatal AIDS Prevention Projects stress HIV prevention related to IV drug use.

In addition, the next phase of the National AIDS Information Campaign, scheduled to begin in May, is directed toward parents and youth and contains messages which address IVDU-related HIV prevention.

Question. How does that percentage reflect the expanding needs for prevention among IVDUs given the changing demographics of new HIV infections?

Answer. CDC has increased funds exclusively targeted to IVDU-related HIV prevention by 33 and 25 percent in fiscal years

1989 and 1990, respectively. In addition, CDC has been expanding activities which address IVDUs within the overall budget available for HIV prevention activities. A major focus for this expansion in resources is increased technical assistance to State and local health departments to develop plans for conducting counseling, testing, and partner notification activities in drug treatment centers and to improve collaboration with drug abuse agencies.

AIDS FTEs

Question. The CDC receives an increase in AIDS FTEs of 112. Is this sufficient to meet the increased responsibilities of these agency for AIDS in FY 90?

Answer. CDC is currently overallocating positions to meet HIV prevention program demands. Since the fiscal year 1990 Congressional budget contains a $94,870,000 increase for CDC's HIV prevention program, the 112 will be required for those new and expanded activities.

Question. This increase in AIDS FTEs is greater than the overall increase in FTEs for the entire agency. What non-AIDS programs will be adversely affected by this transfer of resources to AIDS?

Answer. The increase in FTEs for HIV prevention activities does not represent a diversion at the present time, but an overallocation and, therefore, should not adversely affect CDC's non-AIDS programs.

AIDS COUNSELING AND TESTING

Question. The budget requests $119.4 million for counseling and testing. The justification assumes that the States and localities will pick up two-thirds of the costs. Are States using some of their other federal prevention fund to pay for testing services?

Answer. State and local health departments have traditionally varied widely on the amount of local funding they contribute for HIV counseling and testing programs. Some areas fund these programs far in excess of the Federal portion. Other areas are almost totally dependant on Federal funding. It is difficult to summarize the exact levels of Federal/State/local funding in a particular area since grantees are not required to disclose State and local funding and matching funds are not required in these HIV cooperative agreements. It is also difficult to determine to what extent, if any, these grantees redirect program funds, since PHS regulations do not require prior approval when re-budgeting funds that do not change the program scope.

Question. Would this be the source of their match, even though that is not the intention?

Answer. CDC cooperative agreements for HIV counseling and testing programs have no requirement for either State or local matching funds.

Question. What is the record of these jurisdictions to date?

Answer. Many States and localities provide substantial State and local funds for counseling and testing. For example, California's anonymous counseling and testing program, which provides services to more than 200,000 persons each year, is entirely State funded. The companion confidential counseling and testing program in California is funded by a CDC cooperative agreement. New York City supports many counseling and testing facilities with local funds.

Question. Will they be providing additional funds in FY 90 to match the growth in federal funds?

Answer. There is no way of predicting the levels that States and local areas will use to fund HIV and testing in fiscal year 1990 since there is no matching requirement.

Question. What is the breakdown of costs for testing and counseling?

Answer. Counseling and testing costs are based on the salaries and the fringe benefits of those employees who collect blood specimens, perform laboratory tests, and conduct counseling sessions. Also included are medical supplies, travel, laboratory processing, and other related costs. The cost of a negative test, including pre- and post-test counseling, is estimated to be $43.00. Positive tests including testing, pre- and post-test counseling, and partner notification services are estimated at $92.30.

AIDS ANONYMOUS TESTING

Question. Congress authorized $100 million for anonymous testing under P.L. 100-607. How much of the spending on testing that is projected in FY 90 will be for anonymous, as opposed to confidential, testing?

Answer. The cost to conduct pre- and post-test counseling for either anonymous or confidential testing is the same, however, projects have not been requested to differentiate when submitting budget requests.

Question. The value of testing may be moving beyond being an adjunct to counseling. It is now recommended that those who test HIV-positive receive further tests such as t-cell counts -- to assess whether medical interventions are appropriate. Has the CDC considered whether, as part of its testing program, such follow-up testing is appropriate and what its cost would be if borne at least in part by the CDC?

Answer. T-cell counts do have utility in management of the infected individual. Anyone with an HIV infection and a T-cell count less than 200/ml may need prophylaxis for P. carinii pneumonia. However, since such prophylaxis does not prevent HIV transmission, CDC has no current plans to incorporate T-cell counts into its routine testing programs.

Question. Would such follow-up testing provide useful epidemiological data?

Answer. The primary benefit of T-cell counts is for clinical management of HIV-infected individuals, and the current epidemiologic value of such data is limited.

AZT TREATMENT

Question. Would the CDC consider it appropriate to provide some of those treatments as part of its testing program -- either as a method of treatment or if data show that treatment reduces the likelihood of spreading infection?

Answer. CDC is most interested in the findings of ongoing research regarding AZT treatment for early HIV infection and will wait for research results before considering the need for a policy on provision of AZT at counseling and testing centers. We can speculate, however, on the possible effects of AZT approval for asymptomatic individuals. First, if the findings indicate that AZT delays progression from asymptomatic HIV infection to AIDS, then the need and public desire for early diagnosis through counseling, testing, and partner notification services will accelerate. Secondly, the approval of AZT will place a much greater priority on the need to integrate HIV prevention and clinical services for infected persons. If data become available that AZT can reduce the likelihood of transmitting HIV infection, an additional rationale for early AZT prophylaxis and treatment would exist.

Question. What would the cost implications be?

Answer. The approval of AZT for the indications cited would have substantial budget implications for CDC and other Federal agencies and the States and private insurors. As medical interventions are developed and the benefit of early diagnosis is better appreciated and more widely known, the demand for counseling and testing services are also expected to increase dramatically. There will also be an increased priority placed on partner notification services to ensure that persons exposed receive early diagnosis and appropriate treatment.

STD AND HIV RELATIONSHIP

Question. The relationship between STDs and contraction of HIV has been well documented. The Administration has requested level funding for STDs in FY 90. Will this level of funding permit state health agencies to keep up with an ever-growing explosion of STDs among heterosexuals?

Answer. It is correct that sexually transmitted diseases, especially those that cause genital ulcers, increase the risk of acquisition and transmission of HIV infection. The current resurgence in the United States of the STD causing genital ulcer--primary and secondary syphilis, chancroid, and genital herpes, has occurred primarily among minority heterosexuals. This upsurge has created a critical need to target STD control measures to this population. Primary and secondary syphilis have increased by 17 percent in 1988 over 1987, and represent the largest number reported in any year since 1949. Chancroid increased by 28 percent during the same period. Genital herpes is the main cause of genital ulcers in the United States. Most of these infections are occurring

in minority, inner-city heterosexual populations, the same groups that are at high risk of HIV infection associated with IV drug use. Level funding for FY 1990 will require further targeting of STD resources to those at highest risk to assure that the funds available are used in the most effective manner.

Question. The relationship between STDs and contraction of HIV has been well documented. The Administration has requested level funding for STDs in FY 90. Has an analysis been done of the impact of level funding for STD control on HIV infections in the years ahead?

Answer. An analysis of the impact of level funding for STD control on HIV infections for future years has not been conducted. However, because of the association between genital ulcer disease and sexually HIV spread and the increases in syphilis occurring in populations already with a high prevalence of HIV, it is crucial to insure that HIV prevention activities and resources also be utilized to support STD control activities especially those relating to genital ulcer disease.

RADIATION

Question. How did the Centers for Disease Control get involved with radiation issues? Why have you started working on radiation problems?

Answer. CDC began developing programs in general environmental health and chronic diseases in the early 1970's. Since then, CDC has periodically been asked by various groups (primarily affected citizens, and State and local health departments) to assist in evaluating the health implications of selected radiation problems. These included: a) evaluating the potential for leukemia and other health effects in veterans who served at the atom bomb test site in Nevada, b) the emergency response to the Three Mile Island nuclear reactor incident, c) assistance to ATSDR in assessing the health risks from radiation at selected Superfund National Priorities List sites, d) assistance to EPA in developing a national strategy for radon, and e) evaluation of health risks in communities surrounding selected DOE nuclear facilities.

Question. Why have you started working on radiation problems?

Answer. In spite of the lack of a formal, designated environmental radiation unit, CDC has been called upon repeatedly to assist in evaluating these problems. This suggests that there is some gap or void that CDC is being called upon to fill with regard to public health responses for environmental radiation issues.

Question. Does the CDC have formal, designated responsibilities related to radiation, and, if so, what resources have you had to deal with these?

Answer. In 1979, as a follow-up to CDC participation in the DHHS response to Three Mile Island, CDC was designated as the lead agency within the PHS for coordinating the PHS response to radiation emergencies. During the past 10 years a small number of individuals, working part-time on these radiation issues with

primary responsibilities elsewhere, have carried out these activities for CDC. In 1989, we received an additional $1.5 million and 3 FTE's to work on the study of the health effects of radiation exposure at the DOE Hanford Nuclear Facility in the State of Washington.

Question. It is clear that it is very difficult to maintain sustained activities in a program area that lacks ongoing funding and resources and where individuals are assigned on a part-time, adhoc basis. What is the minimum needed for you to establish a core program to deal with environmental radiation issues?

Answer. CDC's current staff working part-time on radiation concerns serves as its core program to allow CDC to respond to the highest priority environmental radiation issues. Additional staff, perhaps 8 - 10 FTE, with further skills in radiation epidemiology, health physics, environmental monitoring and radiation dose assessment, and statistics and computers could always be used effectively. However, the 1990 budget does not request funding for such expansions in this area, and no offsets have been identified to accommodate any such increases beyond the priorities included in the 1990 President's budget.

NIOSH RESEARCH

Question. What research is NIOSH conducting at Fernald, and what is the status of this research?

Answer. In 1984, NIOSH began an evaluation of an acute uranium exposure incident at the Feed Materials Production Center (FMPC) in Fernald, Ohio (currently operated by Westinghouse Materials Company of Ohio). Although excessive exposure resulting from this incident could not be documented, a number of operational deficiencies were identified and recommendations for improvement were made in a report issued in January 1987.

In response to a union request for a health hazard evaluation, NIOSH investigators reviewed medical and exposure records and subsequently conducted a medical study of workers at FMPC in September 1985. Approximately 150 workers with 10 or more years of service at FMPC participated in the study, which included a detailed questionnaire, urine and blood specimens to measure renal (kidney) function, chest x-ray and pulmonary function tests to assess pulmonary status, and post-shift urine to estimate current uranium exposure. This evaluation, results of which were reported in July 1987 and June 1988, showed no association between various indicators of uranium exposure and renal damage, but it did reveal limited evidence of an association between uranium exposure and pulmonary effects. The environmental chemical and radiological survey was performed by NIOSH investigators to determine employee exposures. Results of this portion of the survey have been put into a report which currently is in final review. The general results of this survey indicated widespread radiological contamination of this facility.

Question. How is NIOSH working with DOE in their occupational health program?

Answer. NIOSH is providing technical assistance and conducting investigations as requested at a number of DOE facilities described below:

1. As discussed previously, NIOSH conducted a health hazard evaluation of an acute uranium exposure incident at Feed Materials Production Center (FMPC) in Fernald, Ohio (operated by Westinghouse Materials Company of Ohio).

2. Portsmouth Uranium Enrichment Complex in Pike County, Ohio (operated by the Goodyear Atomic Corporation).

The industrial hygiene/health physics (IHHP) survey final report was mailed to employer, employee, and DOE representative on December 3, 1987. A copy of this report was also forwarded to Senator Glenn.

The IHHP survey was conducted in six production related buildings where significant radiation exposure potential was suspected. NIOSH provided contamination control recommendations concerning production areas that should be considered for additional emphasis in the contamination control program to DOE. We also recommended that selected data analysis methods be employed for workplace surveillance.

3. Y-12 Plant in Oak Ridge, Tennessee (operated by Martin Marietta Energy Systems).

a. In August 1983, NIOSH was requested by Representatives Gore and Lloyd to evaluate workers who had elevated exposures to mercury in the 1950's and early 1960's while working in one area of this DOE facility. At the time of the request, DOE and their contractor for the facility were already planning to conduct their own medical study. A final report was completed in April 1987. The study found some correlations between declining neurologic function and increasing exposure to mercury. An interaction between aging and neurobehavior effects was seen.

b. On January 7, 1986, NIOSH also received a request from officials of the Atomic Trades and Labor Council (ATLC), who represent hourly workers at the Department of Energy's Y-12 Plant in Oak Ridge, Tennessee. NIOSH investigators found higher than desirable exposures to napthan. A follow-up survey found that exposures had generally declined and symptoms abated.

4. Rocky Flats Plant in Golden, Colorado (operated by Rockwell International).

In September 1984, NIOSH received a request to conduct a health hazard evaluation at the DOE Rocky Flats Plant. The request was submitted by the United Steelworkers of America, Local 8031, concerning a diagnosed case of beryllium disease.
The final report issued in May 1986 reported some over-exposures to beryllium, but normal pulmonary function for current workers. No additional cases of berylliosis were identified among currently exposed workers.

5. Hanford Site in Richland,Washington

In March 1988, NIOSH investigators provided technical assistance to the Department of Energy, Hanford Site, in Richland, Washington. The purpose of the survey was to identify possible deficiencies in their asbestos abatement program. NIOSH investigators made several recommendations to improve the program, but in general they concluded that the asbestos abatement program was very good.

NIOSH RADON PROJECTS

Question . What is NIOSH doing to address the problem of worker exposure to radon daughters?

Answer. NIOSH participated in the MSHA regulatory hearing on August 13-14, 1987, and has submitted three documents to MSHA addressing worker exposure to radon daughters in underground mines. The first document, "Evaluation of Epidemiologic Studies Examining Lung Cancer Mortality of Underground Miners," was submitted May 31, 1985. The second document, "Quantitative Risk Assessment of Lung Cancer in U.S. Uranium Miners," was submitted February 19, 1986. The third document is the NIOSH criteria document, A Recommended Standard for Occupational Exposure...Radon Progeny in Underground Mines, which was transmitted on October 31, 1987.

In the criteria document, NIOSH recommended the current MSHA annual cumulative exposure limit of 4 WLM (Working Lifetime Measure) be changed to NIOSH's REL of 1 WLM, the lowest technically feasible limit. The current MSHA limit is associated with a relative risk point estimate of 2.81 which, based on assumptions detailed in the criteria document, would result in an estimated 42 excess lung cancer deaths per thousand miners. The NIOSH REL is associated with a relative risk estimate of 1.57 which, based on the same assumptions, would result in an estimated 10 excess lung cancer deaths. The REL is the lowest exposure level for which NIOSH found evidence of technical feasibility. NIOSH also made recommendations addressing sampling and analysis strategies, respirator use, and the synergistic effect of smoking, and identified research needs in this area.

During 1988, NIOSH has pursued the potential issues of worker exposure to radon daughters with other experts at CDC. These discussions covered the content of the EPA/PHS joint advisory on lung cancer risks associated with indoor exposure to radon gas and decay products. Additionally, these discussions have led NIOSH to consult with the National Park Service regarding exposures of National Park Service employees in natural caves.

HEALTH OF THE WORKING POPULACE

Question. Have we now decided that the health and safety of the working man or woman in this country is no longer a priority?

Answer. The 1990 budget proposes that continued financial support for occupational safety and health research and training be shared more fully by the States and private industry, which are the major beneficiaries of the results of these activities. In addition, with increasing concerns about the impact workplace

conditions have as causes of, or contributing to, chronic diseases in workers, we believe that industry also has a responsibility and a financial stake, especially because of rising liability costs, to see that research on occupational safety and health issues is conducted and that solutions to protect workers are implemented. Currently, only 22% of occupational safety and health research is conducted extramurally outside of NIOSH. In comparison, about 53 % of total health-related research and development in 1987 was funded from outside the Federal government. This is up from the proportion of 39% in 1977.

NIOSH BUDGET

Question. It is my understanding that the decision made by the Office of Management and Budget to cut for occupational safety and health has been appealed to the Office of Management and Budget. What was the response to that appeal?

Answer. A budget amendment to restore funds for NIOSH research and training has been forwarded by the President to the Congress on May 18, 1989.

Question. Today, more than ever, workers are being exposed to all kinds of chemicals, dusts, and pesticides. The equipment being used in mining, farming, and industry is bigger, more sophisticated, and more powerful. I find it unconscionable that the Administration has taken the position that the federal government no longer has a role in the protection of its workers from occupational injury and disease. What was your original budget submission for occupational safety and health?

Answer. Request for FY 1990 funding for the National Institute for Occupational Safety and Health was in the amount of $102,000,000.

INJURIES IN THE CONSTRUCTION INDUSTRY

Question. Dr. Dowdle, it is my understanding that there are an estimated 1.4 million nonfatal injuries and over 400,000 disabling injuries per year in the construction industry. Do you have any initiatives in place to address the problem of injuries in the construction industry?

Answer. NIOSH is currently spending about $638,000 in FY 1989 on research that uniquely or primarily addresses the problems of injuries in the construction industry and another $20,513,500 on research that is relevant to construction workers as well as other categories of workers. No new initiatives are planned in this area, however.

Question. Do you feel that more needs to be done?

Answer. For FY 1990, NIOSH plans to continue support of several ongoing research efforts.

In the Fatal Accident Circumstances and Epidemiology (FACE) program, NIOSH is studying the circumstances surrounding fatalities due to falls from elevations, contact with electrical energy, and entry into confined spaces, events common to the construction

industry. Risk factors associated with fall-related fatalities will be examined and appropriate intervention strategies developed to reduce the risk of injury from these events.

NIOSH is continuing to develop the National Traumatic Occupational Fatality (NTOF) database which provides surveillance of work-related fatalities and used to identify research needs and direct intervention efforts.

NIOSH is continuing support of the Center for Excellence in Construction at West Virginia University. The Center's overall goal is to promote excellence in construction safety by focusing on education, research and information dissemination specifically targeted to the construction industry.

NIOSH is conducting a broad range of research not directed solely at the construction industry, but which has a significant impact on the health and safety of construction workers. This research covers areas such as use of respiratory protection, chemical protective clothing, motor vehicles, and other equipment; and the prevention of low back injuries and cumulative trauma disorders and recognition and control of chemical and physical hazards.

Question. What are your long-range plans for addressing the fatality and injury rates in the construction industry?

Answer. Available injury data indicate that falls, motor vehicles, machines, and contact with electricity are the leading causes of mortality within the construction industry. In the long run, NIOSH expects research in this area to be focused on:

- Surveillance

  Develop and conduct an extensive survey of traumatic injuries, fatalities, and hazards faced in the construction industry. This would include a program that would generate statistics and circumstances of injuries and fatalities; e.g., the AFL-CIO estimates that about 700 workers loose their lives in trenching accidents each year which are likely due to violations of OSHA standards.

  Extend the Fatal Accident Circumstances and Epidemiology (FACE) program to cover construction fatalities, with particular emphasis on fatal falls, motor vehicles, machines, electrocutions, and collapsing materials.

- Research

  Through field observation of construction tasks and environments utilizing engineering and epidemiologic analysis techniques, evaluate specific injury problems in construction industry sectors with a view toward identifying contributing causal and risk factors.

  Evaluate the use and effectiveness of known intervention techniques, including engineering controls, specific safe work procedures, and protective equipment and clothing.

Support, through grants and other funding mechanisms, demonstration projects implemented through joint labor/management efforts to evaluate NIOSH-recommended intervention techniques and strategies for preventing construction-related deaths and injuries.

Conduct a study to compare the efficacy of prevention programs in the Federal Service Contracts Act and the Occupational Safety and Health Act.

Coordinate research and sponsor international forums with developed countries that have made strides in preventing traumatic fatalities and injuries.

o Intervention

Launch a risk communication campaign which will develop available information on the major known traumatic injury and fatality hazards and methods for prevention. Existing organizations representing various industry, craft, and labor components of the construction industry will be consulted in the development and distribution of informational products.

Promote, through informational campaigns, the widespread use of hazard analysis techniques as a means of anticipating and correcting potential hazardous situations before fatal or injurious incidents can occur.

Influence the adoption of Center-developed professional engineering courses in other civil engineering schools to ensure that largest possible number of engineering graduates are knowledgeable in occupational safety and health concepts, issues, interventions, etc.

Develop a program to certify safety specialists as certified persons for construction and building jobs to include a curriculum for such certification.

Develop case studies of effective prevention programs for the building and construction trades and transmit to OSHA a NIOSH criteria document outlining a model prevention program.

BREAST AND CERVICAL CANCER OUTREACH

Question. We are spending billions of dollars each year on cancer and other disease research. We have learned a great deal about early detection of breast and cervical cancer. West Virginia has the fourth highest rate in the country of deaths related to cervical cancer and ranks sixth in the number of lung cancer deaths. Over 50,000 women die each year from breast and cervical cancer. Inasmuch as technology is present to reduce the threat of cervical and breast cancer, what is CDC doing to provide outreach and education for early detection of breast and cervical cancer?

Answer: At the present time, CDC resources for breast and cervical cancer prevention are directed at improved surveillance,

epidemiologic analysis, and the development and evaluation of intervention efforts. CDC's work is being conducted in cooperation with State health departments, voluntary and professional organizations, and other Federal agencies. These activities will enable the State and local health departments and other organizations to implement interventions to provide early detection of breast and cervical cancer.

CDC is assisting selected States to translate effective technologies into systematic screening programs. These programs focus on screening high-risk populations, providing education to the public and to health care providers, and assuring the highest quality of the screening test. For example, in 1988, CDC provided support to the State of Maine to develop a comprehensive breast cancer screening program that would ensure access to quality screening at an affordable cost for women aged 40 and over.

In 1987, the CDC-coordinated Behavioral Risk Factor Surveillance System began collecting information on the use of mammography screening in participating States. Among all participating States, the range in the proportion of women aged 40 and over who have had a mammogram in the last year was between 15% and 46%, with a median of 30%. State-specific information on mammography use will enable participating States to better plan and evaluate breast cancer screening programs.

CDC is working with other Federal agencies to address the issue of the quality of the screening tests for breast and cervical cancer. For example, CDC is assisting the Health Care Financing Administration (HCFA) to establish cervical cytology laboratory standards and is working with the Food and Drug Administration, the American College of Radiology, and others to establish quality assurance guidelines for screening mammography.

BREAST AND CERVICAL CANCER BUDGET

Question. How much is in this budget to provide for outreach and education for early detection of breast and cervical cancer?

Answer: In the current budget, all funds are directed at demonstration activities for the epidemiologic study of breast and cervical cancer. The State projects described in the response to the previous question will begin to implement intervention activities which will include outreach and education in FY 1990.The 1990 budget includes $1.9 million for the support of these demonstration activities and in-house technical assistance in breast and cervical cancer prevention.

LUNG CANCER

Question. How much is in this budget for outreach and education for early detection and prevention of lung cancer?

Answer: Because there is no proven benefit for early detection of lung cancer, CDC has focused its efforts in the prevention of lung cancer. CDC's FY 1990 budget includes $4,460,000 for smoking and tobacco-related health education efforts, since 80 percent of lung cancer is attributable to smoking.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until 9:30 a.m., Tuesday, April 18, when we will meet in SD-116 to hear from the Alcohol, Drug Abuse, and Mental Health Administration.

[Whereupon, at 12 p.m., Friday, April 14, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, April 18.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

TUESDAY, APRIL 18, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, Adams, and Specter.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF DR. FREDERICK K. GOODWIN, ADMINISTRATOR, ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

ACCOMPANIED BY:

DR. LEWIS L. JUDD, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

DR. CHARLES R. SCHUSTER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

DR. ENOCH GORDIS, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

DR. ELAINE JOHNSON, DIRECTOR, OFFICE FOR SUBSTANCE ABUSE PREVENTION

STEPHEN W. LONG, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

OPENING REMARKS

Senator HARKIN. Good morning. The subcommittee will come to order.

This morning the subcommittee will hear testimony from the Alcohol, Drug Abuse, and Mental Health Administration and the Health Resources and Services Administration.

Within the Department of Health and Human Services, these agencies touch the lives of more Americans than many others. They provide the safety net services to the homeless, the poor, and the neglected. Through these programs and the services they provide, we hope to address the crisis in rural health care, reduce our shameful infant mortality rate, and end the terrible scourge of al-

cohol and drug abuse. Through research on these problems, we strive to make our service delivery network stronger and more effective.

The issue foremost on my mind this morning is the drug crisis gripping this city and our Nation. I just returned from Iowa, and time after time I was told that I should get those people to quit thinking that the drug problem exists only in Washington, DC, New York City, and Los Angeles. Because what is happening in many of our smaller communities in rural America—and I am speaking about Iowa—where they have not had a drug problem before, now they have one. It may not be as big as Washington, DC, but it is something that they have not experienced before, and they don't know how to cope with it. They don't know how to handle it. They don't know what to do, and they are looking for help.

It is affecting our families, our schools, the work place, our communities. As I just said, there seems to be no community untouched by some form of drug abuse. Yet the largest Federal program meant to fight drugs, the alcohol, drug abuse, and mental health services block grant, appears to be hamstrung. We're over 6 months into fiscal year 1989, yet States haven't come close to spending half the funds allocated. Just $100 million of the $806 million block grant has been used thus far.

I spoke with Secretary Sullivan about this, and he shares my concern. We need more than concern, we need some action. As a lead agency in the fight against drugs, the Alcohol, Drug Abuse, and Mental Health Administration must take charge of this situation and work with States to mobilize their efforts.

Our first witness is Dr. Frederick Goodwin, Administrator of the Alcohol, Drug Abuse, and Mental Health Administration. I am especially interested in what you have to tell us about progress in the area of drug abuse prevention. I am committed to targeting our resources toward effective programs to turn this situation around, and I want to know from the experts what programs and treatments work best. ADAMHA has made research a top priority, I understand, and we are looking forward to learning more about progress in this area, just what you are doing in this area and how you balance that with the need to provide services.

Dr. Goodwin, your entire statement will be placed in the record. Would you please introduce your colleagues, the institute directors, and if you would summarize your remarks, I would certainly appreciate it.

[The statement follows:]

STATEMENT OF DR. FREDERICK K. GOODWIN

I am pleased to appear before you to discuss the President's fiscal year 1990 budget request for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). The enormous and urgent public health challenges posed by mental illnesses and alcohol and other drug use disorders, which cost $50 billion annually for clinical care alone, dictate the high priority that ADAMHA attaches to refining and expanding the Nation's capacity to treat these conditions.

The emphasis our request places on strengthening ADAMHA's scientific programs reflects our confidence that research constitutes a sound and cost-effective approach to enhancing the quality and availability of care, to which ADAMHA contributes through a program of Block Grants to the States, and to improving strategies for preventing the onset or reducing the severity of mental and addictive disorders. This latter task is being pursued through basic and clinical research, some of which I will discuss later, as well as through the prevention demonstration programs supported by ADAMHA's Office for Substance Abuse Prevention.

The priority of our scientific mission warrants a brief comment. When ADAMHA was founded, the bulk of its resources were dedicated to the direct support of community-based mental health and substance abuse treatment programs, an important and successful emphasis, but one which severely curtailed the resources available to the Agency for research support. The impact of our reduced research purchasing power from the late 1960s to the late 1970s was magnified by the fact that the public sector, and predominantly ADAMHA, is the sole source of support for more than 85 percent of biomedical and behavioral research on mental and addictive disorders.

Over the past decade, scientific opportunities have combined with a growing awareness of the societal implications of these clinical problems to stimulate an accelerated rebuilding of ADAMHA's research programs. This reorientation has been facilitated by the ADMS Block

Grant, under which States have assumed their rightful role in managing their health care delivery systems.

The accomplishments and initiatives which I will discuss today are the products of a research investment which represents less than 1 percent of the amount our Nation spends annually on services for the mentally ill and for treating those who abuse alcohol and other drugs. Even short of a "breakthrough," the investment is critical because it provides legitimacy and focus to our mandated national leadership role. Research, moreover, is the most potent tool we have for generating valid bases for hope that mental and addictive disorders are amenable to treatment and for destigmatizing these disorders.

Our sense of accomplishment over specific progress the Nation has made in addressing the clinical--and resultant social--problems of substance abuse and mental illness must be tempered by an awareness of the magnitude of the problems which persist. At any one time, 15 percent of the adult population is suffering from a diagnosable mental disorder or an alcohol or other substance abuse disorder, and six-month prevalence rates for these conditions are 19.1 percent. Some 13 to 18 percent of Americans under age 18 have mental disorders, many of which persist into adulthood.

Precise epidemiologic data have sharpened our appreciation of "comorbidity;" that is, the extent to which mental and addictive disorders tend to co-occur and, consequently, compound the human and economic costs associated with discrete conditions. We know, for example, that among the estimated 300,000 to 600,000 persons who are homeless on any given night, as many as one-half are mentally ill, frequently suffering schizophrenia, and 35 to 40 percent also suffer from alcohol or other drug problems. We know that an unrecognized and, thus, untreated major depressive disorder in an adolescent or young adult significantly increases the likelihood that the individual will abuse drugs--perhaps in an effort to self-medicate his or her depressive disorder. This information suggests that the early

identification and treatment of clinical depression is a very direct way of combatting substance abuse. Information on comorbidity permits us to refine prevention strategies and provide national leadership on the design of optimally effective and appropriate service programs.

Drug abuse remains a critical public health problem, although signs of progress in combatting the scourge are evident. The 1988 High School Senior Survey found drug use by seniors to be at its lowest level since the annual survey was begun in 1975. We are particularly encouraged by a continuing decline in rates of cocaine use. Over the past 4 years, we have seen a 50 percent drop in the proportion of seniors who report current use of cocaine. A principal factor underlying this trend is the scientific basis of our education and prevention messages. Most young people find research evidence of brain damage drawn from animal and clinical studies credible and, thus, persuasive; research on general health consequences is having a similar impact. On the other hand, among the 12 percent who ever have used cocaine, more than two in five have used crack. We have grounds for concern that these students will end up in that subgroup of the general population whose drug use patterns are becoming more compulsive and more damaging. One measure of the damage is found in data from the Drug Abuse Warning Network, (DAWN) which tracks negative health consequences and deaths due to drug abuse: In 1987, cocaine use resulted in more than 46,000 emergency room cases in DAWN hospitals, up from 25,000 in 1986.

More than 35 percent of the high school seniors had five or more alcoholic drinks in a row in the two weeks preceding the 1988 survey. Early exposure and heavy use patterns help to explain why alcohol abuse continues to be a factor in nearly half of all accidental deaths, suicides, and homicides in the U.S., including 42 percent of all deaths from motor vehicle accidents.

Although AIDS is consolidated into a single PHS account, the disease is central on the ADAMHA agenda, particularly within NIDA.

Nearly one-third of all new cases of AIDS are occurring in intravenous drug users, and nearly 70 percent of babies born HIV-positive have mothers who themselves are intravenous drug abusers or whose sexual partner is. The NIMH applies its unique programmatic focus and expertise on brain and behavior to a comprehensive AIDS research program that encompasses studies of fundamental processes, clinical studies, and research on individual and social behavior aimed at strengthening the only proven means of prevention currently available--behavioral change. And NIAAA examines the implications of alcohol abuse for AIDS, through ethanol's effects on the immune system as well as on the disinhibition of behavior, including sexual behavior.

In the face of these challenges, the clinically-inspired basic research and treatment and prevention studies supported by ADAMHA are yielding promising results. Particularly exciting is research being conducted by each of our Institutes that involves studies of fundamental processes which appear to be driven by genetic anomalies. These leads are promising given the implications of well-defined genetic markers for targeting prevention to vulnerable individuals.

In mental health, investigators have identified a link between schizophrenia and an abnormality on chromosome 5 in seven families with many schizophrenic members. Other studies have identified possible genetic markers for manic depressive disease on chromosome 11 and on the X-chromosome. The fact that some studies did not find these particular associations suggests that these diseases and their variants have multiple genetic bases. Further studies of these disorders based on such linkages are likely to unravel their underlying genetic mechanisms and offer ways to diagnose, predict, and prevent them.

NIAAA researchers have confirmed that a component of the vulnerability to alcoholism is inherited. Using the techniques of molecular biology, researchers now are attempting to learn where, in the human genome, this vulnerability lies. There is also evidence that susceptibility to the medical consequences of chronic alcohol abuse is

inherited in some cases. It has been discovered that a specific form of the gene that produces collagen, a protein found in connective tissue in the body, is associated with alcoholic liver cirrhosis. This finding presents an opportunity for developing a non-invasive diagnostic test to identify alcoholics at risk for cirrhosis and for devising specific molecular approaches to treat the disease.

In research on drug abuse, we have found that some strains of animals are more prone than others to take cocaine or opiates. Research now in process to understand the neural basis for this genetic predisposition will help us to understand vulnerability to addiction.

Brain imaging technologies have emerged, in a few short years, as essential workhorses of the research enterprise. Our scientists have used magnetic resonance imaging (MRI) to compare the brains of identical twins, one of whom has schizophrenia, and demonstrated that enlarged ventricles are a characteristic feature of the disease. Complementing this finding are the results of single photon emission computerized tomography (SPECT) scans which have shown that, compared with normal controls, the frontal lobe activity of schizophrenic patients is reduced as they try a cognitive task. Patients with the most severe frontal lobe deficits are also those with enlarged ventricles and more pronounced "negative" symptoms of schizophrenia. We also have found, again through the use of MRI, that a part of the cerebellum (a region responsible for balance and coordination) is abnormally small in autistic patients; how these structural findings in the cerebellum might explain defects in the way autistic patients respond to their environment is now under study.

An advantage of the ADAMHA configuration is that it fosters cross-fertilization of knowledge in disparate fields. For example, basic animal studies conducted by NIMH scientists investigating brain mechanisms involved in manic depressive illness have demonstrated that chronic use of cocaine causes a condition called "kindling" wherein spontaneous firing of neurons increases the likelihood of sometimes

lethal seizures. This work suggested use of the anticonvulsant drug, carbamazepine, to prevent cocaine-kindled seizures. Preliminary clinical studies have demonstrated the efficacy of this treatment.

To address these challenges, the 1990 Reagan budget requested a total of $1.6 billion of which $774 million was to be distributed directly to States through block grants. Within the overall budget, we struck a balance between fully funding research proposals and maintaining a stable number of grants. Under the mandated Block Grant set-aside, ADAMHA will conduct data collection, and health services research as well as provide technical assistance, all activities needed to accumulate knowledge needed to determine which treatment and prevention approaches work best. ADAMHA has a major role in two of President Bush's initiatives: combatting drug abuse, and assisting the homeless. The 1990 Bush budget proposes $765 million to support drug abuse research, prevention and treatment activities, including $65 million for two new initiatives: a community partnership prevention effort, and a new program to support provision of drug treatment services. The proposal also increases to $64 million funding for ADAMHA programs authorized by the McKinney Homeless Assistance Act. In addition, the consolidated budget proposal for the Office of the Assistant Secretary for Health includes $218 for ADAMHA's AIDS programs.

Finally, our budget request includes $18 million for the annual subsidy payment for Saint Elizabeths Hospital. This subsidy is to assist the District of Columbia in assuming full operational responsibility for the hospital as authorized by Public Law 98-621.

I will be pleased to answer any questions you may have.

BIOGRAPHY OF DR. FREDERICK K. GOODWIN

Frederick K. Goodwin, M.D., became administrator of the Alcohol, Drug Abuse, and Mental Health Administration July 26, 1988. He was nominated by President Reagan June 23, 1988, and confirmed by the Senate July 22.

Dr. Goodwin is responsible for leading and coordinating federal efforts to provide scientifically based solutions to the public health problems associated with mental illness, alcoholism and drug abuse. ADAMHA is composed of three research institutes — the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health — and the Office for Substance Abuse Prevention.

A specialist in psychiatry and psychopharmacology, Dr. Goodwin served as scientific director of the National Institute of Mental Health and director of the institute's intramural research program from 1982 to 1988. He joined the NIMH staff in 1965. His clinical research interests have focused primarily on biological and psychological factors in clinical depression and in manic depressive illness. He was the first to report the antidepressant effects of lithium in a controlled study.

Dr. Goodwin also has become involved in AIDS research. From 1986 to 1988, he served as AIDS coordinator for ADAMHA and chairman of the Subgroup on Neurosciences and Behavior of the Public Health Service AIDS Executive Task Force.

Dr. Goodwin was born in Cincinnati, Ohio, April 21, 1936. He received his bachelor of science degree from Georgetown University, 1958; his M.D. from St. Louis University School of Medicine, 1963. He served his psychiatric residency at the University of North Carolina at Chapel Hill.

Dr. Goodwin is a member of numerous professional societies, including the Institute of Medicine of the National Academy of Sciences, and serves on the editorial boards of many journals in his field. He is the recipient of major research awards, including the Hofheimer Prize, the A.E. Bennett Award, the Taylor Manor Award, the International Anna-Monika Prize and the Edward A. Strecker Award. In 1986 he was awarded the highest honor available to a member of the career federal service: The Presidential Distinguished Executive Award.

Dr. Goodwin has authored more than 375 publications and is one of only five psychiatrists on the Current Contents' list of the most frequently cited scientific authors in the world. His clinical skills are widely recognized; he is one of 12 psychiatrists listed in the Best Doctors in the U.S.

He is married to Rosemary Goodwin, a clinical social worker with expertise in alcohol and drug abuse treatment. They have three children. The family residence is in Chevy Chase, Md.

BIOGRAPHY OF DR. LEWIS L. JUDD

Lewis L. Judd, M.D., was appointed in January 1988 as Director of the National Institute of Mental Health (NIMH), the largest scientific institute in the world with a primary focus on mental disorders. Whereas NIMH has a long history of distinguished directors drawn from public service and academia, Dr. Judd is the first active scientist to head the Institute. Previously, Dr. Judd served 11 years as Professor and Chairman of the Department of Psychiatry in the School of Medicine at the University of California, San Diego (UCSD), and as Chief of the Psychiatry Services at University of California Medical Center, San Diego.

Dr. Judd is an expert in the field of biological psychiatry and clinical psychopharmacology. His extensive research experience includes focuses on psychotropic drug effects on brain mechanisms, the cytogenetics of severe mental disorders, and studies on depression, manic-depressive illness, and schizophrenia. He brings to the directorship a broad and rich experience with NIMH over the years, both as a grantee and as a member and chair of many scientific review and advisory committees, including the NIMH Board of Scientific Counselors.

As a clinical research scientist, Dr. Judd has been a prolific contributor to the world's scientific literature, and has served on the editorial boards of many distinguished scientific journals, including the American Journal of Psychiatry, the Journal of Clinical Psychiatry, Psychiatry, and the Journal of Neuropsychiatry and Clinical Neurosciences. He also edited the recently published book The Basic Science Foundations of Clinical Psychiatry.

A veteran who served as a Captain in the United States Air Force, Dr. Judd also brings to his Federal position extensive experience as Chief of the Psychiatry Service, then as Senior Consultant in Psychiatry, at San Diego Veterans Administration Medical Center. In addition, he chaired the Veterans Administration Research Review Committees on Mental Health and Behavioral Sciences.

Dr. Judd received his bachelor of science degree in psychology from the University of Utah. He earned his medical degree with honors from the School of Medicine at the University of California at Los Angeles (UCLA), where he was elected to Alpha Omega Alpha, the honorary society for medicine. He served an internship in internal medicine and residencies and fellowship in psychiatry and in child and adolescent psychiatry at the UCLA Center for the Health Sciences in Los Angeles. Upon completion of his post graduate medical training he joined the faculty at UCLA, where he held a dual academic appointment in the psychiatry and psychology departments. Dr. Judd was Director of Education in Child and Adolescent psychiatry at UCLA prior to his being recruited to UCSD.

Dr. Judd is a member of the Scientific Council of the National Alliance for Research in Schizophrenia and Depression and is a member of numerous professional and scientific societies, including the Society for Neuroscience, the Psychiatric Research Society, the Association of Academic Psychiatry, the West Coast College of Biological Psychiatry (President 1985). He is a Fellow of the American College of Neuropsychopharmacology and of the American Psychiatric Association, and he was recently elected to membership in the Institute of Medicine (National Academy of Sciences).

BIOGRAPHY OF DR. ELAINE JOHNSON

For the past sixteen years Elaine M. Johnson has held several key leadership posts in the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). She was named Director of the Office for Substance Abuse Prevention (OSAP) in February 1988.

In this capacity, she manages OSAP's alcohol and drug abuse prevention programs. This includes large demonstration grant programs, community assistance programs, and communications and knowledge transfer initiatives, including the National Clearinghouse for Alcohol and Drug Information. OSAP also provides workshop and conference support to national, professional, and community-based organizations to augment their prevention programs.

Prior to joining OSAP, Dr. Johnson served as Deputy Director of the National Institute on Drug Abuse (NIDA) beginning in June 1985. In this role, Dr. Johnson helped to administer the Institute's scientific program and expand its research on cocaine. She also helped to create new programs to address the problem of acquired immune deficiency syndrome (AIDS) and played a key role in developing NIDA programs to respond to the President's anti-drug initiatives.

Dr. Johnson played a principal role in the White House Conference for a Drug Free America, serving as both the Moderator and Director of the Drug Abuse Treatment Committee. She has also served as a consultant to the U.S. Department of State, the U.S. Information Agency, and the Department of Defense in several countries in Europe, South America, Central America, and Asia.

She is the recipient of numerous governmental, professional, and civic awards, including most recently the National Medical Association Award for Outstanding Leadership in Improving Health Care in the Black Community; the National Association of State Alcohol and Drug Abuse Directors Award for Outstanding Service in the Drug Abuse Field; and the National Drug Information Center of Families in Action Prevention Award for Defining and Advancing the Science of Prevention.

Dr. Johnson received her Baccalaureate degree from Morgan State University in Baltimore, Maryland, and both her Master's and Ph.D. degrees from the University of Maryland.

BIOGRAPHY OF DR. CHARLES R. SCHUSTER

Dr. Schuster, 59, is an internationally recognized researcher on the psychopharmacology of drugs of abuse. For the past decade, he has been an Expert Advisor to the World Health Organization for the international regulation of drugs of abuse. Prior to joining the National Institute on Drug Abuse (NIDA) in March of 1986, Dr. Schuster was the Director of the University of Chicago's Drug Abuse Research Center, and Professor of Psychiatry, Pharmacological and Physiological Sciences, and Behavioral Sciences in the University's Medical School. He has authored or co-authored over 150 scientific journal articles, as well as numerous book chapters and several books.

Dr. Schuster served as the Acting Chairman of the University of Chicago's Department of Psychiatry while at the University of Chicago. This appointment reflects his accomplishments and stature.

From 1963 to 1968, he conducted research in psychopharmacology at the University of Michigan, where he held posts as Assistant and Associate Professor of Pharmacology.

In 1968, Dr. Schuster became Associate Director of the Illinois Drug Abuse Rehabilitation Program. While there, he was instrumental in developing a new program to rehabilitate drug users. He also administered a methadone maintenance clinic and a polydrug abuse clinic for adolescents, and conducted clinical drug studies.

Dr. Schuster received his Ph.D. from the University of Maryland, his M.S. from the University of New Mexico, and a B.A. from Gettysburg College, Pennsylvania.

He is a member of numerous professional activities, and serves as consultant to many committees and organizations in the drug abue field at the national and international level. He is a Fellow of the American Association for the Advancement of Science, American College of Neuropsychopharmacology, and the American Psychological Association.

BIOGRAPHY OF DR. ENOCH GORDIS

Enoch Gordis, M.D., became the Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in October 1986. Prior to this, he was a staff member of the Elmhurst Hospital in Elmhurst, N.Y., where he directed the hospital's alcoholism program from 1971 until his appointment to NIAAA; and was Professor of Clinical Medicine at Mt. Sinai School of Medicine, New York City.

The NIAAA, a part of the Department of Health and Human Services' (DHHS) Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), leads the Federal effort to prevent and treat health-related consequences of alcohol use. This is accomplished through the conduct and/or support of research, research training, data collection activities, and a wide variety of information dissemination activities. The Institute also conducts and supports studies on alcohol-related policies; and is responsible for providing DHHS decisionmakers with state-of the-art analyses of the impact of national policies on preventing and reducing alcohol abuse and alcoholism, and recommendations for new and/or revised policies. The Institute budget for FY 1989 is $114.1 million.

A recognized expert on alcoholism treatment, Dr. Gordis has written extensively on a variety of alcohol-related research and clinical topics including treatment outcome research, ethanol and methadone drug interactions,

disulfiram therapy in alcoholism, and alcoholism and drug addiction in pregnancy. He also has served as a member of an ADAMHA Committee on Reformulation of Definitions of Alcohol and Alcohol Abuse, as a site visitor for the National Institute on Drug Abuse, and as a member of the NIAAA Alcohol Psychosocial Research Review Committee. Additionally, Dr. Gordis is an active member of the Research Society on Alcoholism and the American Medical Society on Alcoholism and Other Drug Dependencies, and serves on the Editorial Review Board of the Journal Alcoholism Clinical and Experimental Research.

As NIAAA Director, Dr. Gordis' principal goal is to continue support for activities designed to give maximum visibility to the Institute's role as a leader in alcohol-related research and the integral part of that role in preventing and treating alcohol abuse and alcoholism. This will include continued support for NIAAA's intramural and extramural research programs, including those which provide training opportunities in alcoholism research; increased attention to public policy research; and enhanced data collection and dissemination activities.

A member of Phi Beta Kappa, Dr. Gordis received his B.A. degree from Columbia University in 1950 and M.D. degree from the Columbia College of Physicians and Surgeons in 1954. He is a member of the American Physiological Society, the American Federation for Clinical Research, Sigma Xi, the American Gastroenterological Association, and Fellow of the American College of Physicians.

Dr. Gordis maintains residences in Rockville, Maryland, and New York City, New York.

BIOGRAPHY OF STEPHEN W. LONG

Stephen W. Long became the director of financial management of the Alcohol, Drug Abuse, and Mental Health Administration May 26, 1988.

Mr. Long is responsible for the formulation, presentation, and execution of a $2 billion budget and over 1700 Federal employees. The Federal budget he is responsible for supports research, treatment, and prevention programs for the mentally ill, alcoholism and alcohol abuse, and drug abuse. ADAMHA is composed of three research institutes--the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse and the National Institute of Mental Health--and a fourth entity the Office of Substance Abuse Prevention.

Prior to becoming the director of financial management for ADAMHA, Mr. Long served as the principal financial and planning advisor to the Director of the National Institute on Alcohol Abuse and Alcoholism from 1977 to 1988.

Mr. Long joined the Federal government in 1970 as a program analyst for the Medicaid program. He was nominated for the Department of Health, Education, and Welfare Financial Management program and spent a year at the University of Pittsburgh's school of Public Administration. Between 1972 and 1977, Mr. Long worked as a budget analyst in the Public Health Service.

Mr. Long was born in Cranston, Rhode Island, July 22, 1946. He received his bachelor of arts degree from the University of Rhode Island, 1969.

He is married to Theresa Ballicha, a public information officer at the National Heart, Lung, and Blood Institute of the National Health Institutes. They have two children and their residence is in Bethesda, Maryland.

INTRODUCTION OF ASSOCIATES

Dr. GOODWIN. I appreciate having the entire statement in the record, Mr. Chairman. Since this is the first time ADAMHA has been before you, I would like to take the opportunity to make a few comments about our mission and our history and about how research, prevention, and treatment fit together.

The colleagues that are with me: On my immediate right is Dr. Lewis Judd, Director of the National Institute of Mental Health; on the left is Dr. Charles Schuster, who is the Director of the National Institute of Drug Abuse; Dr. Enoch Gordis who is the Director of the National Institute of Alcohol Abuse and Alcoholism; Dr. Elaine Johnson who is the head of the Office for Substance Abuse Prevention; and Stephen Long who is our budget officer. I would like to also introduce Dennis Williams from the Department Budget Office.

The people I just introduced represent, I think, the best team we have ever had. They come from academic backgrounds with strong research experience, and they have also had practical experience in actually running programs, running departments, and running treatment programs. Dr. Johnson, who is the former deputy director of the Drug Abuse Institute, is ideally suited to do the critical job of translating what we know into actual real world prevention programs.

My own background is that of a scientist. I have been a scientist in the government for 25 years, mostly in the field of depression and manic depressive disorder, but I have also been a clinician treating patients. As a clinician, I can certainly agree with your assessment that the problems that ADAMHA faces: The mental disorders and the alcohol and drug disorders are, indeed, very serious; they are a major drain on our financial resources, on society's safety network, as you said.

EXTENT OF ALCOHOL AND SUBSTANCE ABUSE PROBLEMS

One example of that is the fact that schizophrenia accounts for over 20 percent of supplemental social security income payments; the mentally ill, alcoholics, and drug abusers are a very substantial drain, just on unemployment rolls alone. So, the economic and other societal consequences of these disorders are very, very substantial.

Now, I would like to draw your attention to the charts at the end of the table. I will also give you a copy of them. They show the results of a very large NIMH epidemiological study which indicates that the lifetime incidence of mental disorders is about 22 percent. In other words, at some time in their lives, 22 percent of the people will have a mental health disorder. For alcohol abuse, the figure is about 13 percent; for drug abuse, it is about 6 percent.

This data would not be available without a reliable diagnostic system. We know what these disorders are. Trained clinicians know how to diagnose them. We have just as much agreement in measuring these disorders as physicians do in agreeing about the presence of a physical disorder. The notion that the prevalence of these disorders is debatable is no longer tenable. We have made substantial progress in developing diagnostic systems. This has

really been the fruit of a long effort in clinical research to figure out how to diagnose these disorders and how to get people to agree about that. We also know that these disorders involve biological, including genetic, and psychosocial forces.

The data you see here means, among other things, that, at any given time, about 15 percent of the population has a mental disorder, alcoholism, or drug abuse, or some combination thereof.

CONTRIBUTION OF RESEARCH

The epidemiologic research that has produced these data has also given us some resounding research advances. For example, recently in NIMH, scientists combined epidemiologic findings with information about gene markers and discovered a specific gene for manic depressive illness which afflicts about 2.5 million people in this country for whom we can now provide relatively successful treatment.

Clinical advances have come in parallel with astounding advances in the neurosciences. In fact, it was early ADAMHA investigators who laid the groundwork for much of modern brain science. Julie Axelrod, who won the Nobel Prize, is a long-term NIMH employee, and Saul Snyder, who is a long-term NIDA grantee, won the Lasker Award.

In addition to these clinical research advances in neurosciences, we have seen a revolution in psychopharmacology. Today the outlook for a patient with manic depressive illness is dramatically improved. Before lithium was discovered some 20 years ago, people with manic depressive illness spent about one-fourth of their adult life in the hospital, and another one-fourth in other disabling circumstances. So, one-half of the lives of these millions of people was spent disabled. Now, 80 percent of such people are well and functioning at a normal level. The savings from that one treatment alone, which started with an animal study and went on to systematic clinical investigations, have been about $12 billion in direct health care costs. The research investment was less than 1 percent of that $12 billion savings.

The tragedy, though, that is illustrated in this chart is that, even with the existence of lithium and other successful treatments, most people who need treatment are not getting it. Less than one-third of those with ADM disorders are in treatment, compared to two-thirds of those with the medical disorders for which NIH is responsible.

We think that is a measure of stigma. We think that public misunderstanding about these disorders, including the mistaken assumption that they indicate character flaws, has inhibited the access to care for many of our patients. One of the reasons we take our research mission so seriously is that findings from research help get rid of stigma and superstition. Once you have solid research data, you can go to third party reimbursers and say, "Look, this is really an illness. We can diagnose it. Treatment actually works."

Research in these disorders especially is a Federal responsibility. In the physical disorders that the NIH treats, 45 percent of the funding comes from private sources; in our disorders, only 10 per-

cent. So, we are practically the only act in town when it comes to supporting research, and that is one of the reasons we give particular emphasis to that. Also, back in the 1970's when we had a tremendous push in our agency to establish large service programs, research suffered. Some of the knowledge gaps that we have now, particularly in the treatment of drug abuse and alcoholism are related, I think, to having let our knowledge base slip a little bit 10 or 15 years ago.

COMORBIDITY OF ADM DISORDERS

Now, let me call your attention back to that first chart in order to close with a comment about why it is that the mental health, alcohol and drug abuse institutes are together in the same organization. These problems coexist in the same people; and we call this comorbidity. You can tell from the chart, for example, that over one-half of drug abusers have at some time had a mental disorder. In three out of four of those cases, the person starts with a mental disorder and goes on to drug abuse. In one out of four cases, drug abuse complicates a mental disorder.

Now, what does that tell us about prevention? It tells us that one part of drug abuse prevention is research on early detection and early treatment of mental disorder. That is one reason Dr. Judd has invested so many resources in detecting childhood and adolescent depression. If such people are allowed to stay depressed and untreated, they are going to be twice as likely to end up abusing drugs.

Or take alcohol abuse. One-third of alcohol abusers have a mental disorder. Moreover, alcohol can complicate the mental disorder. That chart shows that about 65 percent of the seriously mentally ill have a drug or alcohol problem. Of course, those drug or alcohol problems render people resistant to effective treatment.

So, we think research on comorbidity is one important thing we can do to contribute to prevention, real focused prevention, and to contribute to development of better treatments.

We would be happy to elaborate on any of these points or some of the issues that you raised in your opening statement.

PRIVATE VERSUS PUBLIC FUNDING SOURCES

Senator HARKIN. Thank you very much, Dr. Goodwin.

You said that 45 percent of the research at NIH comes from private sources, but almost all that you get comes from the Government sources.

Dr. GOODWIN. That's right.

Senator HARKIN. Alcohol, drug abuse, and mental disorders have an equal economic impact in terms of lost hours and lost wages. It seems to me that this kind of research should bring in the private sector just as much as research on physical ailments.

Dr. GOODWIN. What really happens is that those who have mental or substance abuse disorders, or whose family members have them, have not been so effective in advocating their causes. They have been in the closet, so to speak. Only recently we have seen groups like the National Alliance for the Mentally Ill, Parents

for a Drug Free America, the National Council on Alcoholism, beginning to say:

> Look, these things are health problems. They are not simply character weakness. They are not simply social or legal problems. They have those aspects, but they are fundamentally health problems. We need as much research on them as we do on diabetes, as we do on arthritis, et cetera.

In fact, I think it might be fair to say that the people that are affected with these kinds of problems are not as close to the mainstream and perhaps they have less impact on what happens.

Senator HARKIN. I can understand that I guess. I wonder where most of those private sources come from. Foundations and things like that?

Dr. GOODWIN. Yes; for example, the American Heart Association and the American Diabetes Association. Also, there is a fairly substantial investment in research from the pharmaceutical industry for development of new drugs for the treatment of those disorders.

RESEARCH VERSUS SERVICES

Senator HARKIN. Well, again, I am just getting into this whole area. I've served on this subcommittee now for 4 years. And I remember the former chairmen, Senator Weicker and last year Senator Chiles.

There seems to be a—I don't know if conflict is the right word—tug perhaps between research and services in your area. What I hear the most about are the services. I don't have too many researchers coming to me. I have a lot of people out there that are on the services end of it. There are those who say that you are putting too much of your time and your effort and our money into research and not enough into services. How do you respond to that?

Dr. GOODWIN. Well, let me first point out that the research budget, as a percent of the total service cost of these illnesses, is less than 1 percent. So, one could convert the entire research budget into service programs, and it wouldn't even be noticed. It would be a blip.

Senator HARKIN. One percent of your budget?

Dr. GOODWIN. No; not 1 percent of our budget. I was saying the cost of research is equal to 1 percent of the direct care cost of these disorders. The Federal Government's role in health care delivery in the mental and addictive disorders is about 17 percent. Funding for health care delivery, as you know, is a mixture of public and private; in the public sector, it is a mixture of Federal, State, and local. But putting aside what is spent through Medicare and Medicaid, if you just take categorical expenditures for the mental and addictive disorders at the State and local and private levels, our research is about 1 percent of that.

Senator HARKIN. Of the total that is spent out there?

Dr. GOODWIN. Right.

My point is that we are spending a very small amount on research when compared to the physical disorders; a very small amount as a percentage of the total health care cost. If you look at health care costs, not indirect costs, but just the direct treatment costs of alcoholism, drug abuse, or any of the major mental illnesses, and look at what we have spent on research as a percentage of

what direct treatment cost, the percentages are substantially lower than for any of the disorders that the NIH studies—any of them. For example, one rare neuromuscular disorder gets about 100 times the research funding that schizophrenia gets, relative to the cost of treatment.

So, I am very sensitive to the concerns about what we do about service delivery. Certainly the Federal Government has a very important role in providing national leadership. ADAMHA has a very important role through its block grants, and we have seen a 25-percent increase in the block grants from 1988 to 1989. We have sustained that increase in this budget. We have tried to reshuffle the block grants to pay more attention to the drug abuse problem. We have an IV drug abuse set-aside particularly to attend to that very serious problem and its connection to AIDS.

But overall I think it would be shortsighted to shift any of the research moneys into services because we simply don't know enough about what it is that we are delivering. The real question is not just how much service we can deliver, but rather: How good is the service we deliver, what is the quality of it, and how much do we know about what works. Until we know more, we are going to have to continue efforts on the research front or else we will simply be consigning ourselves to delivering things which are necessary but which aren't of the quality or effectiveness that we could deliver if research were sustained.

The example I gave you of lithium is not an exception. It's simply an example. Had we not been able to sustain research in that over all those years, we would, indeed, still be treating manic depressives by hospitalizing them at enormous expense and at an enormous loss of quality of life.

EVOLUTION OF THE ADAMHA MISSION

Senator HARKIN. The problem is NIH—their only mission is research.

Dr. GOODWIN. Yes.

Senator HARKIN. But you have a dual mission.

Dr. GOODWIN. Historically we have been through several phases. The precursor of ADAMHA was NIMH when it was responsible for drug abuse, alcohol, and mental health. It was one of the four original institutes of the NIH and it had lots of national leadership responsibilities. It did demonstration projects. Then in 1967, NIMH was moved out of NIH in order to facilitate creation of community mental health centers around the country. We built those community mental health centers around the country. We built a structure of care.

But, gradually, we began to realize that having done that, we needed to know even more about what it was we were doing. We needed to have solid data. We began to lay down that data base that I was talking about, being able to diagnose these disorders, being able to say they are, indeed, disorders, looking at the biological factors, looking at drug treatments, looking at psychotherapy, and how they interact.

Then in 1981, when the block grants were created, our categorical service programs were, in effect, turned over to the States with

a modest amount of Federal responsibility in keeping track of how the money was being spent. In the 1986 and 1988 Drug Acts, we were given new responsibility to pay attention to particular areas: To collect data, to give technical assistance, and to do a kind of practical research on how services were actually being delivered. All of these things are very important.

But essentially, we are now back in the posture, with the exception of the block grants that go through our agency, of having as our primary mission research, including disseminating research results, teaching clinicians and practitioners of all sorts, and providing national leadership.

Now, national leadership doesn't mean a lot unless you have data to back it up. It doesn't help me when I go down to HCFA to argue about reimbursement for the mentally ill or alcoholics if I don't have data. And they look at it very critically to see what might be cost effective.

Senator HARKIN. I get a feel for that. I guess it's just the idea of how much are you moving in the direction of research and really not paying attention to the mission of providing services. It is my understanding that aside from collecting data and putting out the block grants, that your mission is also to provide leadership, direction, and guidance.

Dr. GOODWIN. That is a critical thing. Sometimes people think of research as something that is off in the lab or in a university clinic. That is an important type of research.

But research also includes examination of very practical questions about what works in the real world. We have a large increase in our budget for research demonstration projects in the substance abuse area. Dr. Schuster and Dr. Gordis could describe those projects. For example, we take what we already have learned from a university setting and see how it actually applies in the real world, and we are using block grant set-aside funds to start what is called service systems research. In other words, we are learning through research how better to deal with these disorders. It is not necessarily laboratory research. It is not necessarily locked away in the university.

BASIC RESEARCH VERSUS OTHER RESEARCH

Senator HARKIN. If I were to look at your budgets for the last couple of years to see how much you are spending on what I might call in a layman's term field research as opposed to lab research——

Dr. GOODWIN. Yes; that is a good distinction.

Senator HARKIN [continuing]. Would this be increasing at a greater rate than lab research?

Dr. GOODWIN. Yes; the two things that are increasing are field research and AIDS research.

Senator HARKIN. What are you doing with AIDS?

Dr. GOODWIN. We are doing various experiments on brain changes induced by AIDS, and on how to change behavior in order to avoid AIDS. Of course, the biggest problem with AIDS is IV drug abuse—the fastest growing contribution to the AIDS epidemic. We have a lot of activities in this area: How to outreach to these

people, how to give them AIDS messages, et cetera. The biggest potential payoff in reducing AIDS is to treat IV drug abuse more effectively. That is why NIDA is devoting so much of its resources to the development of new treatments for IV drug abuse.

But what I was going to say, Mr. Chairman, is that if you take the AIDS budget away, our so-called laboratory, or basic research budget, is increasing by about 3 percent. It is not keeping up with inflation. Field research and demonstrations is the area where we have had our biggest enhancement.

Senator HARKIN. Now, Dr. Goodwin, it says in the budget justification for ADAMHA, page 26, "Basic research has increased by 9.2 percent over fiscal year 1989 while applied research has increased by 1 percent."

Dr. GOODWIN. Yes.

Senator HARKIN. Is this what you are discussing?

Dr. GOODWIN. Yes; but as I said, if you take out the AIDS budget, the non-AIDS portion is only 3 percent for the nonapplied research.

Senator HARKIN. Basic research.

Dr. GOODWIN. Yes.

Senator HARKIN. Well, that is three times as much an increase as for applied research. It says applied research has increased 1 percent.

Dr. GOODWIN. Well, it may be a matter of semantics. What I was talking about was the demonstration projects, which are substantially enhanced, and the set-aside from the block grant which I don't think was counted in those figures.

Senator HARKIN. Maybe I don't understand all your terminology, and you don't understand mine.

I said that if I looked at lab research as opposed to field research, that field research would be going up more than lab research. But the justification says no. It says that basic research has increased by 9.2 percent. You say if we cut the AIDS out, maybe it is only 3 percent. But applied research has increased by 1 percent.

Dr. GOODWIN. In budget terms, both the basic and applied numbers you refer to are included in our research line. I am referring to the budget items which appear under demonstrations and block grants. These affect our ability to go out to the field to generate new knowledge and test theories in real life situations. In fiscal year 1989, our OSAP budget, which is mainly this type of demonstration, doubled to $70 million and we are asking for $72 million in fiscal year 1990. We also have a new $40 million program through the use of the block grant set aside to do health services research and data collection which we were not doing before. In that respect, our field research has increased dramatically in the last year.

Those are things that don't show up in our so-called applied research budget. But they fit your definition, I think, of field research.

So, if you look at the whole range of ADAMHA activities, the only parts that are pure service delivery with no ability to collect information as we go, would be the bulk of the block grant, the 95 percent that is not in the set-aside.

TECHNICAL ASSISTANCE TO THE STATES

Senator HARKIN. ADAMHA's 1990 budget request cuts technical assistance to States—the alcohol, drug abuse, and mental health services block grant. Well, it was a small cut.

Dr. GOODWIN. Yes; we had this very large increase from 1988 to 1989, 25 percent. So, in effect, funding from 1988 to 1990 has not been reduced.

Senator HARKIN. I want to get down to what I am really honing in on, and that is how we are dealing with the States.

We have the alcohol and drug treatment and rehabilitation block grant, that was in the 1986 drug bill, to give States a shot in the arm to fight drug abuse. This money came on top of the funds States were already receiving in the mental health service block grant.

Dr. GOODWIN. Right.

Senator HARKIN. Of the $319 million we appropriated for the ADTR block grant in fiscal year 1987 and 1988, I understand that $87 million, 27 percent, is still in the bank, not yet spent by the States, and eight States haven't even spent a penny of their 1988 funds.

Clearly, having two block grants for dealing with drugs was too cumbersome, so in the 1988 drug bill, Congress consolidated the two block grants into one grant, the alcohol, drug abuse, and mental health services block grant.

But even with one block grant, there seems to be a problem. Of the $805 million we appropriated in fiscal year 1989 for this block grant, just $100 million has been spent. So, here we are 6 months into the year already, and only 13 percent of the funds have been spent.

I understand that some States must have their legislatures approve the spending and that States have had some problems setting up programs to use these funds. But what is the Department doing to move this money into the pipeline?

Dr. GOODWIN. Those numbers are a little better than they looked a few weeks ago when Secretary Sullivan testified. In fact, 44 percent of the 1988 money——

Senator HARKIN. Pardon?

Dr. GOODWIN. Forty-four percent of the 1988 ADTR money has been drawn down. You are correct, however, in saying that eight States still haven't drawn down any of their 1988 money. The 1987 money is virtually all drawn down, 92.5 percent.

Essentially, what these were——

Senator HARKIN. Let me just get this straight. So, 44 percent of the 1988 money is drawn down.

Dr. GOODWIN. Is drawn down, right.

Senator HARKIN. But there are eight States that haven't.

Dr. GOODWIN. Right. And for 1989, you see, the pace is picking up. Essentially, I think what happened here is that States had startup problems with the 1987 and 1988 ADTR funds.

Senator HARKIN. How good are those figures, that 44 percent?

Dr. GOODWIN. Well, they are very up-to-date, and they have been carefully checked.

Senator HARKIN. My staff got the 13 percent figure yesterday.

Dr. GOODWIN. That is 1989.

Mr. LONG. That is 1989. The 13 percent is the 1989 ADMS drawdowns. The 44 percent is 1988 ADTR drawdowns.

Senator HARKIN. Let's get this straight. OK, 1988 funds we said 27 percent.

Dr. GOODWIN. That is up to 44 percent now.

Senator HARKIN. I said $87 million is not spent, 27 percent is not spent. So, you say that more than that has been drawn down. Then there is something wrong here.

We had $319 million in fiscal year 1987 and 1988. And $87 million has still not been spent by the States. That is 27 percent of the total.

Mr. LONG. Thirty-one percent of the 1987 and 1988 combined is not drawn down.

Senator HARKIN. So, what is this 44 percent figure you are using?

Mr. LONG. The 44 percent is for 1988 alone.

Senator HARKIN. How much is that?

Mr. LONG. The dollar amount? It's $68 million; $68 million is drawn down out of $156 million that was appropriated.

Senator HARKIN. Out of how much?

Mr. LONG. Out of $156 million that was appropriated.

Senator HARKIN. Well, then what has happened to the $319 million minus the $156 million for 1987?

Dr. GOODWIN. Almost all of that is drawn down already.

Mr. LONG. It is just how you are counting the money. We were talking about——

Senator HARKIN. We lumped it together, and you are separating it out.

Mr. LONG. Right. The figures reconcile.

REASONS FOR DELAYED STATE DRAWDOWNS

Dr. GOODWIN. My point in looking at it year by year is to show the trend. We think what happened is that the States had startup problems. The ADTR money was allotted with 2 years to spend it. Many of the States, I think most of the States, thought it would be one-time money. In a sense the signal from Washington was to go slow because this was one-time money and should be spread over 2 years.

In addition, many States were required by State law to pass legislation before the money could be spent. States also had to go through competitive bidding processes. Also, many States wanted to coordinate this with block grants from the Justice Department and the Education Department.

And, if you look at what happened to the ADMS block grant—the established block grant—the drawdown rates are quite acceptable. And yet, when that block grant was first allocated, there was slowness as well. So, I think we may be dealing with a start-up problem.

You asked, though, what we are doing about that. I have asked my staff to see if there is anything in our Federal procedures that could be changed to speed up the process. And I would certainly be happy to get back to you on that.

Senator HARKIN. OK. But basically we still have 1987 and 1988 money that has not been drawn down.

Dr. GOODWIN. Yes.

Senator HARKIN. In 1988 it looks like you are telling me you have $88 million of 1988 money. Am I right?

Dr. GOODWIN. That's right.

Senator HARKIN. And for 1989, we have—now, did you have a different figure? I was concentrating so much on 1988. I said in 1989 my staff got a figure from you just yesterday that said only $100 million has been spent.

Dr. GOODWIN. That is right. Some 43 States and Puerto Rico have applied, 37 awards have already been issued. Seven States and the District of Columbia have not applied at all yet for 1989. They are some of the same States that haven't spent their 1987 money yet.

But, I agree that there is a problem with drawdowns. I think the attention that Congress is giving to this is beginning to make a difference in the State governments. The statutory formula was complicated. And States have established procedures which they must follow.

We continue to provide technical assistance. We have already this year held three national conferences to provide help to the States, three workshops on how to deal with this somewhat complex formula and other problems.

We are experiencing the same kinds of start-up problems with the homeless block grant. Only 36 percent of that money has been drawn down. Again, we think these are largely start-up problems. Once these activities are underway, and particularly when States can count on having the money for more than 1 or 2 years at a time, I think we will see this pick up. But we are looking at anything that we can do to speed it along.

Senator HARKIN. If a community in Iowa tells me that they have experienced an increase in drug abuse in their community, but they really don't know what to do about it, and they are looking for some help and assistance, I tell them that we put $1.2 billion into a program in 1988 and 1989.

Senator BUMPERS. Unfortunately, if you gave the States the money, they still wouldn't know what to do to prevent drug abuse.

Senator HARKIN. Well, what I am saying, Senator Bumpers, is that somebody is supposed to take a leadership role in drafting guidelines and trying to determine the best way of spending these moneys. And if no one is doing it, then why are we appropriating the money?

DATA ON THE DRUG ABUSE PROBLEM

Senator BUMPERS. I didn't mean my earlier remark to be flip. We really don't know the best strategy for preventing drug abuse.

Dr. GOODWIN. I think we can come back to that. I think there is a lot of concern about what to do about it. There is a lot more information about that than I think is generally appreciated. Dr. Schuster and I would be glad to elaborate on that in a minute.

But on this issue of IV drug abuse set-asides, for example, there is a procedure whereby States that don't have a large IV drug abuse problem can request a waiver for the IV set-aside portion.

And, in fact, we are in a position to act rather quickly within 2 to 3 weeks. We have requested OMB clearance for that procedure already. Any State that wants a waiver and can demonstrate that they don't have the problem for which those set-aside moneys were created would be granted a waiver.

Now, to your question about how States could spend that money: The problem is being addressed through the technical assistance and the data collection that is being provided. That was, I think, the wisdom of that set-aside; it enables us to fill the gap between the knowledge we have from controlled studies and what people who are implementing programs know.

Senator HARKIN. Let me ask you a question about data collection. What portion of the field research you are doing involves coordination with social service agencies?

Dr. GOODWIN. Well, we can answer from two perspectives.

Senator HARKIN. Let me finish my question. I'm just trying to think of all the different people who are involved in this. To find out what correlation there is between the increase in drug abuse and the family structure and what has happened in that family over the last few years in terms of unemployment, family breakup, and homelessness. Are you collecting this kind of data?

Dr. GOODWIN. Well, there are two different perspectives to that. Dr. Schuster can talk about what NIDA is doing about drug abuse data collection and Dr. Johnson can talk about coordination efforts to get various community groups together to look at family structure issues and how that relates——

Senator HARKIN. It would seem to me that would be a fairly easy collection of data, would it not?

Dr. GOODWIN. No; because there often are not standardized methods in place for assessing issues like whether there is a coexisting psychiatric problem in the family. Let's say a mother or a father is very depressed. There often is not a good system in place for getting the information about those coexisting problems.

Senator HARKIN. Why don't you standardize such a thing? Why don't you do that?

Dr. GOODWIN. That is what some of our research is about. Another question is how to disseminate those research findings. We can set guidelines and standards, and we do. We now have, for example, a standard diagnostic system that everybody who works with clinical populations is supposed to follow. It's the basis for reimbursement for third-party payors. And that, as I suggested earlier, has come from research.

Senator HARKIN. But your answer to me—when I ask you if you have an ongoing program of collecting data and trying to find out if there is a correlation—is, yes.

RECENT DATA COLLECTION ACTIVITIES

Dr. GOODWIN. Just recently. In other words, up until the Drug Abuse Act of 1988, in effect, the Federal Government did not have authority to collect such data from the States. Our role was to put the money out there and to hold States accountable for it, but we were not allowed to collect other data from the States.

That has been changed by the 1988 Drug Act. So, as of October, yes. As of just last October, we are in a position to begin to collect this data, but we are not in a position to begin to draw conclusions from it because we have just started to collect it.

But, if you are interested, Dr. Schuster could describe some of those data collection activities and how we think that that will provide answers better than we have today.

Dr. SCHUSTER. Well, first of all, as Dr. Goodwin has said, up until 1981 we did have in place a variety of survey techniques for monitoring what was going on in drug abuse treatment. After 1981, those systems were essentially dissolved.

Senator HARKIN. Why?

Dr. SCHUSTER. Because, under the block grant formula, the States no longer had to report to the Federal Government on who was coming into treatment, what the nature of the treatment was, how long they were staying, and so forth. Those systems as part of the block grant——

Senator HARKIN. Then they keep that data on local and State levels?

Dr. SCHUSTER. Yes and no. Some of the States have continued to do it. Some essentially altered the system so that when we attempt to get them to voluntarily provide us with information, the information that they provide us is not in a useful form. Some people comingle alcohol and drug abuse, so we can't collate it in terms of looking at it from the Federal perspective.

Dr. GOODWIN. It should be noted that along with the change in the categorical programs, there was about a 25-percent reduction in overall funding during that 2-year period. So, the States had less resources with which to work. And perhaps data collection was one of the things that was sacrificed.

Dr SCHUSTER. Well, that is exactly right. The administration felt that since it no longer required this type of data, that funds provided by the Federal Government could be decreased because those responsibilities were no longer placed upon the States.

What we are doing now is to take our experience prior to 1981 and combine it with the modern technology of computer science so that we can get a better picture of exactly what Federal Government dollars are being spent for. Let me very briefly try to explain to you the activities we are engaging in.

The first thing that we have to do is determine the total census of treatment programs that are providing drug abuse and alcohol treatment. We are doing this through the National Drug and Alcohol Treatment Unit Survey [NDATUS]. From this survey, we know that there are roughly 5,500 different programs that are receiving some form of Federal Government assistance. And we have a description of the services provided by those programs. We know whether they are designed for alcoholism or drug abuse or both; how many clients they see; and what is their budget.

EFFECTIVENESS OF DRUG TREATMENT

It would be very difficult for us to collect data on all the people that come in to the treatment systems. But because we know the total population, we can draw samples from that population of

treatment programs that will be representative of therapeutic communities, methadone maintenance treatment programs, and various types of drug-free outpatient programs. From that sample, we can conduct an intensive analysis of the nature of the clients who are coming in, on the appropriate diagnostics as Dr. Goodwin said. Other issues we will analyze include what kind of treatment are patients receiving; how long are they staying in treatment—that is a major problem; what kind of outcomes are being achieved; and what are the costs of treatment and is it cost effective.

So, from the general population of treatment programs, we will draw samples to do specific studies about the nature of the treatment process itself and hope in the future to be able to provide you with more accurate data in terms of what the Federal Government dollars are buying.

We are concerned that treatment programs in the United States from 1981 on may have deteriorated. Recent research studies which we have done of seven methadone maintenance treatment programs have shown extreme differences with some being excellent and some being very poor.

That study also provided us with information on the characteristics of good programs and of those that are doing a poorer job. We are currently exercising national leadership by making this information available to the States and to treatment programs. We need more of this kind of data to be able to get an assessment of the quality of drug treatment programs today. What is the variance in the quality of programs? Are some programs very good, are some very bad? Why are those bad programs bad? Are they dealing with a population that is harder to deal with, or are they simply less effective? We need to improve their effectiveness.

Senator BUMPERS. Mr. Chairman, would you yield for a question?

Senator HARKIN. Sure.

VULNERABILITY TO ADDICTION

Senator BUMPERS. In the past few years, has drug abuse become more prevalent among the lower economic classes? There is a correlation, isn't there, between the environment and drug abuse?

Dr. SCHUSTER. Yes; certainly we know that individuals who have fewer alternatives, less options, in terms of what can engage their behavior are more prone to become involved in drugs.

Senator BUMPERS. Is there any decline in drug use among the upper middle class?

Dr. SCHUSTER. Yes; there is.

Senator BUMPERS. There is?

Dr. SCHUSTER. Yes; I have a slide on cocaine dependency that illustrates this.

Senator BUMPERS. Is that the slide on cocaine dependency?

Dr. SCHUSTER. Yes.

Dr. GOODWIN. Maybe while that is up there, I might explain this briefly. When we are talking about addictive disorders—this would include alcoholism as well as drug abuse—you have to consider two different spectra of vulnerability. One is the environmental vulnerability. If a person is in an environment in which there is no way to get rewards or feel good in a normal sense, he or she is more

likely to succumb to drugs once having experimented with them because it is the one thing that can make that person feel good.

There is also biological vulnerability. We know in alcoholism, for example, there is a highly genetic form of the disease where a person is going to be addicted from the time they have their first drink, and they have no chance ever because their brain is wired in such a way to cause them to become addicted very quickly. That is about 20 to 25 percent——

Senator BUMPERS. And that is an inherited vulnerability?

Dr. GOODWIN. That is an inherited gene among alcoholics, about 20 to 25 percent of them. It's early onset.

Now, what happens is that environmental and genetic factors interact. Somebody who comes from a very bad environment needs hardly any biological vulnerability to be vulnerable to addiction. If you have somebody—illustrated, let's say, way out on the right side of the blue line there—he or she could have very low biological vulnerability and yet be highly prone to addiction.

Similarly, if you have somebody who comes from a nice, upper middle class, suburban neighborhood and who has a supportive family and a good education, that person could become vulnerable to drug or alcohol abuse if he or she is genetically vulnerable. But it takes more genetic vulnerability to bring that out.

You asked whether drug abuse is down in the mainstream population. Yes; it is going down. Drug abuse is settling down into the more and more vulnerable segments of the population, including those with coexisting psychiatric disorders, including those who come from environments where they have very little to lose and relatively more to gain from drug use.

I think that the high school survey indicates that very clearly. Maybe Dr. Schuster wants to describe that.

DRUG ABUSE AMONG YOUTH

Dr. SCHUSTER. We have an annual survey, the national high school senior survey, in which we interview about 16,000 high school seniors asking them about their drug use in terms of 11 categories of drugs, including alcohol and tobacco. In addition, we ask them questions about their attitude toward drug use. Do they consider it dangerous? Do they associate with people who use drugs and so forth?

We have found that, for most drugs that are used in the United States, the peak of the drug abuse epidemic was reached in about 1980. At that time, for example, 11 percent of high school seniors were smoking marijuana on a daily basis. That is 11 children out 100 were smoking marijuana every day. In 1988, that figure was less than 3 percent.

Similarly, PCP use in the country has fallen by better than 50 percent from the peak in 1980. Cocaine, however, as you can see from this chart which covers years from 1975 through 1985, continued to increase until 1985. Then in 1986, 1987, and 1988, we see this decline in the number of students who report that they are current users of cocaine, that is, that they have used cocaine at least once in the past 30 days.

Now, let me point out that, of course, about 25 percent of children who start school in the United States never finish it. In the major cities, the number of high school dropouts can be as high as 50 to 55 percent. We know from other studies that, among high school dropouts, drug use is two to three times as high as it is in those who reach their senior year of high school. So, although high school students are obviously a very important segment of our society, the high school survey does not get at the segment most at risk and most vulnerable to drug abuse, and that is the inner city ghetto children who have dropped out of school and who are using drugs at a much higher rate.

EPIDEMIOLOGY OF COCAINE ABUSE

Senator HARKIN. Cocaine consequences are going up. Is that because there is more use among a smaller population?

Dr. SCHUSTER. Well, there are two things. That is correct.

First, with cocaine there has been a switch from snorting cocaine to smoking it. The toxicity and addictive properties of smoked cocaine, commonly used in the form of crack, are much more intense than from internasal cocaine. So, we see more emergency room visits because people can more readily get into toxic dose levels, the high doses that produce heart attacks, that produce convulsions, that produce all kinds of medical consequences.

Second, many of the people who began their drug use back in the late 1970's and early 1980's, during the period of time when cocaine use really took off in the United States, those people started experimenting with cocaine and it has taken them 2 or 3 years to intensify their habit to the point where they became addicted and are ending up in the emergency room. There is always a lag between the initiation of drug use and the time that individuals get so intensively into it that it produces these kinds of consequences.

Dr. GOODWIN. Also, animal studies show that the longer an animal is exposed to cocaine, the more likely the abuse will result in violence, so that what you are seeing in the crime statistics is the effect of the peak from 1985. Those same folks are now 4 or 5 years older. They have been using drugs 4 or 5 years longer. Their brains are that much more disrupted. In an animal, if you repeatedly give it the same dose of cocaine, its brain will get more and more sensitive to the drug. Eventually the animal will have convulsions or exhibit some other violent behavior.

So, we think that the attention given to the increased crime rate is partly a function of increased pathology from drugs, but not of increased incidence of drug use. Those are two important things to keep distinct.

Senator BUMPERS. What would the bottom half of that chart look like for the general population?

Dr. SCHUSTER. Well, among those who are 12 to 18 years of age, we believe usage is also going down.

For financial reasons, we have only been able to collect our household data about every 2 to 3 years. Now, with the new set-aside funds that have been provided in 1988, we will be conducting it on a yearly basis.

We have just come out of the field with our 1988 survey. The results will be available soon. Hereafter, we will have them on a yearly basis.

Dr. GOODWIN. We would be happy to get back to the committee with those results as soon as they are available.

Senator BUMPERS. I would certainly like to see those as soon as they are finalized.

DRUG THERAPY FOR SUBSTANCE ABUSE

Dr. GOODWIN. Perhaps in a month from now.

Senator BUMPERS. Mr. Chairman, I'm going to have to leave. I just wanted to ask Dr. Goodwin one question.

When Jimmy Carter was Governor of Georgia and I was the Governor of my State, we had a Governors' conference in Georgia. He was very anxious to show his fellow Governors a large methadone center in his State. Subsequent to that visit, I read that the methadone centers in the country were being closed because we were just changing addicts' dependency.

First, what is the status of methadone now? Second, how much are we spending to develop a drug to block cocaine, for example?

Dr. GOODWIN. Oh, yes; I think they might. [Laughter.]

Dr. GOODWIN. I disagree with you on that.

Senator BUMPERS. Well, I am pleased to hear that because I have a feeling that the private sector is spending little in this area of drug development.

Dr. GOODWIN. That is a different problem. The reason they are not is because they worry about diversion and some of the legal encumbrances that are on drug development if it is an addictive disorder.

But there are essentially two pharmacological approaches to treating drug addiction. First, is the methadone approach which is an attempt to find a safe, medically administered substitute for a self-administered drug. And I think that methadone works very well in the control studies. Of the 50 percent of people who stay in methadone treatment, the relapse rates are quite low. The dropouts relate to all the societal problems that these people come to the clinic with and you can't expect methadone itself to take care of.

The other pharmacological approach—and this is where we think a Nobel Prize winner may well come from, but probably not from a drug company laboratory—is changing the chemistry of the brain in a way that modifies abnormal craving. In other words, as a result of genetic factors in some humans or in humans who have been on drugs for a while, change in brain functioning may occur. Just as an epileptic's brain functioning changes to produce convulsions, a person who is addicted to drugs suffers brain changes. If we can find a way to correct that chemical imbalance through drugs, that could bring the craving down to a manageable point so that psychological and psychosocial strategies could have a chance to work.

The problem with cocaine treatment now is you get these people into these treatment centers, and 90 percent of them are gone within 1 year because their biological craving for the drug is so

strong. The ones who stay, particularly upper middle class people who have a lot to lose from going back, do very well. Effective treatment centers use things we have learned about tricyclic antidepressants to reduce craving in combination with psychosocial strategies to help desensitize the patient to the drug. It's sort of like getting allergy shots, where you get a little bit of exposure over a period of many years. That's what you do. You expose the person gradually to the stimulus, and the craving gradually goes away. So, the 10 percent who stay in treatment do very well, but the dropout rate is great.

FUNDING FOR NEW DRUG DEVELOPMENT

So, NIDA, for example, is investing—thanks to the 1988 drug bill—$10 million more in drug development. It is something that the Government has to do because the drug companies are not likely to pick this up until they see that it can be done with relatively little hassle and with a likely payoff.

Senator BUMPERS. I must confess, $10 million for a problem of this magnitude doesn't seem like very much.

Dr. GOODWIN. No; it doesn't.

Senator BUMPERS. I am just curious as to whether or not we could use a lot more.

Dr. SCHUSTER. It is estimated that to bring a single drug to market, the cost to the pharmaceutical industry is $125 million over a period of 7 to 8 years with the help of highly skilled people. Although the 1988 Antidrug Abuse Act provided only $10 million, we also have some of our general research dollars devoted to this. Our total program is closer to $20 million. However, that level of funding is very low, particularly in future years when research is moved from the laboratory to clinical trials, which is where the big cost comes in.

We do have, as Dr. Goodwin said, several very promising candidates which may modify the craving for cocaine.

Senator BUMPERS. I am encouraged to hear that. I didn't know how much research was going on in that area. And frankly, I didn't think it was enough.

Dr. GOODWIN. We would be happy to supply for the record an estimate of what the scientific establishment could absorb in this.

Senator BUMPERS. I wish you would do that.

[The information follows:]

DRUG RESEARCH

In fiscal year 1989 NIDA will spend approximately $20 million on the development of new medications for the treatment of drug abuse. Of this amount, $10 million was provided by the Anti-Drug Abuse Act of 1988 and $10 million is from our regular research appropriation. All of the $10 million from the Anti-Drug Abuse Act and approximately $3 million from our regular appropriation will be spent on new starts in fiscal year 1989. Almost all of these projects will have continuation costs in fiscal year 1990.

We estimate that we could award approximately $16 million on new starts in the medications development program in fiscal year 1990. New starts would be initiated in the following areas: Research in synthetic and medicinal chemistry to identify new compounds for the treatment of drug abuse; open and blind clinical trials of compounds for the treatment of cocaine abuse; clinical trials to compare LAAM to methadone; phase II trials of buprenorphine; long-term toxicity testing of a buprenorphine-naltrexone combination; phase I testing of a combination of buprenorphine

and naltrexone; animal testing to examine the possible toxicity of several medications proposed for the treatment of cocaine when they are taken in conjunction with cocaine; and phase I trials of a depot preparation of naltrexone.

IMPORTANCE OF ANIMALS TO RESEARCH

Dr. GOODWIN. It is certainly a small amount compared to the amount we have invested in developing cancer treatments, for example.

I might point out, by the way, that one of the things we are most worried about in this regard is that the animal rights activists have targeted drug abuse researchers because they feel that the public assumes that research on the chemistry of the brain is trivial to understanding drug abuse. That assumption is based on the notion that drug abuse is a result of character weakness or purely social conditions. Nothing could be further from the truth.

In fact, a recent, very exciting development in the treatment of cocaine craving, which is just getting an early clinical trial, is the use of an anticonvulsant. One of Lew Judd's investigators in the Mental Health Institute found that cocaine could produce convulsions in the brain. He tried an anticonvulsant in animals, and indeed it wiped out not only the convulsions but the craving the animal developed for cocaine. That has now been tried in a clinic in Minnesota. It never would have occurred to anybody in the cocaine field to think of using an anticonvulsant if it hadn't been for that animal study.

We are very concerned that the demoralization and fear that is being created among drug abuse researchers by the animal rights activists is going to slow down their willingness to get into this area. Like most researchers, they have other options for what they could be doing with their time and don't need the hassles involving research with animals. We would appreciate your efforts in supporting that kind of research.

Senator BUMPERS. You certainly will have my support.

VALUE OF PREVENTION PROGRAMS

As I say, fighting drug abuse is a frustrating proposition. We are never going to interdict more than a small percentage of the drugs coming into the country. Therefore, reducing the demand for drugs is the key.

It seems to me that development of drugs to prevent addiction could assist in reducing drug use and abuse in a dramatic way.

Dr. GOODWIN. Could I just add something about the issue of supply interdiction? The data from the high school survey—that is, the mainstream 50-percent reduction in serious drug use over 4 years—was in the face of increased supply. The kids said it is easier and easier to get, but they are less and less interested.

Now, those mainstream kids turning away from drugs, I think, is a palpable and deliverable result from the prevention efforts that have been underway. I think the programs that the Office for Substance Abuse Prevention is running can show kids that research proves that marijuana gets in their brains and sticks there for days and weeks at a time; this refutes the notion that marijuana is another safe recreational drug. It is from this kind of hard-nosed re-

search that mainstream kids are really beginning to get the message. Now, we have to do much more to get to the ones who are not in the mainstream and who have so many other problems, including mental disorders. It is not a matter of just reducing the supply. As I said, prevention works in the face of an increased supply.

Senator BUMPERS. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bumpers.

DRUG ABUSE AMONG DROP-OUTS

Just to follow up on the survey that you are doing. You say that you will have the data from the survey of high school students?

Dr. SCHUSTER. I'm sorry?

Senator HARKIN. The household survey.

Dr. SCHUSTER. Yes; the household survey—the last one was completed in 1985. We have just finished collecting the data for the 1988 survey. It is being analyzed and the results will be available soon.

Senator HARKIN. Did the survey include any children younger than 12?

Dr. SCHUSTER. Not in that specific survey, no. However, we do support research grants that look at drug use in children from the age at which they enter school on.

Senator HARKIN. Just to follow up on Senator Bumpers question on the high school situation regarding who is using the drugs, you said that the drug use is going down. That is the good news. But research conducted by the National Institute on Drug Abuse found that the rate of illicit drug use among 19- to 21-year-old high school dropouts was 67 percent higher than for graduates of the same age.

Dr. SCHUSTER. Correct. That is what I was saying when I said this data is only representative of those children who are fortunate enough to reach their senior year in high school.

Also, we would like to point out, sir, that the data from Denise Kandel, a NIDA grantee in New York City, indicates that it is a two-way street. Dropouts use more drugs, but drug use is responsible for a significant number of those children dropping out. And that is an important consideration.

PROTECTED ADAMHA PROGRAMS

Dr. GOODWIN. Before Senator Bumpers leaves, I would like to make one more point about the issue of the research role that is being played in prevention and treatment.

The ADAMHA research budgets for NIMH and the Alcohol Institute were, we think, inadvertently left out of the protection from the flexible freeze that was afforded the NIH institutes across the board. We think that was because the Bush budget was focusing on some high priority and highly visible enhancements in our budget for homeless demonstrations for the mentally ill and for new drug abuse demonstrations. We think this may have been an oversight; clearly, our behavioral and biomedical research is every bit as important to protect as is the NIH research. We hope that the Senate will help redress that problem.

Senator BUMPERS. They forgot a lot of things. [Laughter.]

They forgot, for example, that 60 percent of the inner city children in this country aren't even immunized against measles and polio. I will start a sermon if I don't leave. [Laughter.]

THE ALCOHOL PROBLEM

Senator HARKIN. We have to leave here for a vote very soon, but I want to get away from hard drugs, illegal drugs, and talk about the legal drug that we use in this country that is available to almost everyone, and that is alcohol.

A recent poll of 8th and 10th graders revealed that 77 percent of 8th grade students have used alcohol, and 55 percent of those students first tried it by age 6. The 1988 survey of high school seniors showed that 64 percent of them use alcohol regularly and 35 percent had been on a drinking binge within the last 2 weeks.

Is alcohol more of a threat than illegal drugs?

Dr. GOODWIN. Well, as you recall from the discussion of comorbidity, they often coexist so that there are certain similarities.

Senator HARKIN. Not only coexist. One of the pieces of data that I have seen showed that almost 100 percent of those who used hard drugs have previously used alcohol.

Dr. GOODWIN. Yes; it is considered a gateway drug, and it certainly lowers inhibitions against other things.

There are some encouraging trends. Daily use of alcohol is down in the high school survey. Perhaps Dr. Gordis could comment on where he feels the alcohol problem is in general because it remains a major public health problem.

Dr. GORDIS. It is a very extensive problem. And the youthful component of it, as you said, Mr. Chairman, is a very distressing aspect of it.

As Dr. Goodwin stated, the high school survey which addresses the same kind of kids that Dr. Schuster spoke about shows somewhat of a drop in the daily or most extreme form of alcohol use among kids.

There is no question that alcohol in its own right is very troublesome. It leads to school dropout. It leads to police problems, and the stunting of the normal adolescent emotional growth. And so, it has that role in itself, aside from the fact that it is a disinhibitor and leads to the use of other drugs at the time that the kid's judgment has been impaired by it.

In general, I think it is not wise to compare the severity of alcohol and drugs. I think both are very serious problems. Alcohol-related problems can be perhaps most colorfully illustrated by the data indicating that about 20 to 40 percent of all adult hospital beds in this country are occupied by people being treated for the results of their drinking. This is not alcoholism treatment itself. This is the consequences of the drinking, liver disease——

Senator HARKIN. Car wrecks.

Dr. GORDIS [continuing]. Car wrecks, trauma, liver disease, heart problems, anemia, et cetera.

Disease, of course, is just one piece of the cost of alcoholism. The other aspects are the tremendous loss of productivity and the tremendous social costs in maintaining impoverished families and jail sentences for those who are violent while drinking and so on.

The issue of young people and drinking is not an issue of clinical alcoholism. Very few clinically diagnosable alcoholics exist among the teenagers. It happens occasionally. I've seen it. But by and large, we are talking about trouble from alcohol in kids who might be getting into trouble of a general nature. Therefore, we come to the broader issues of adolescent development, of risk taking, of availability of alcohol, and of the way society actually views the way the messages about alcohol will be delivered to our younger population.

There is no single factor, I think, which is going to correct it all. But I think the tendencies that Dr. Goodwin alluded to indicate that society is becoming less tolerant of the excessive consumption of alcohol and, if we have some time or if you are interested for the record, we could elaborate on that further.

STATE SPENDING OF FEDERAL ANTIDRUG MONEY

Senator HARKIN. Senator Specter.

Senator SPECTER. Thank you very much, Mr. Chairman.

When Dr. Sullivan was in last week, I brought to his attention a model project on the homeless which is currently being formulated in Philadelphia; a detoxification center, some counseling and some beds, both detox beds and also residential treatment center beds. I just wanted to alert you gentlemen to it this morning because we are in the process of putting together such an analysis.

It originated when Secretary Kemp visited the homeless center on Ridge Avenue. Secretary Kemp, Senator Heinz, and I found a large group of relatively young men, in their late 20's, 30's, 40's, who needed help and who could be put back in the work force. These men are different from many of the homeless, and I wanted to alert you to that.

I am aware of the article in the New York Times yesterday about the States not using the antidrug money, and it is a subject which has been on my mind for a long while. When Secretary Bennett was Secretary of Education last year, he was in and I asked about that issue. I have worked very closely with Governor Casey in Pennsylvania to see to it that the funds have been requested.

At the time that Secretary Bennett was in, which I think was in the spring of 1987—yes, we passed the first drug bill in 1986, and this was the spring of 1987—the funds had not been requested. Pennsylvania hadn't made the request. We had a new administration in the State. I raised the issue with Secretary Bennett that I thought it was a Federal obligation to go to the States and to see to it that the States made the applications.

I am surprised to see very many prominent States which have apparently good State administrations which have not made the applications on the allegation of paperwork. I can tell you, and I know Senator Harkin will confirm this, that it is the congressional intent that these moneys be wisely spent. We don't want them just spent, we want them wisely spent. But we do want them spent.

To have this $775 million available—and I tracked through the $25 million with Pennsylvania. I have said to Governor Casey and his people that I would like to see tangible results because if he can show tangible results, we can get him more money. The Congress is

willing to pay for results. Congress is unhappy about paying under any circumstance, but especially when we see waste or when we don't know what is happening.

There are two points which I would like to make and they are related. One is that I would hope that your unit will regard it as your duty to go to the States and see to it that they are applying for the money. And then, of course, the secondary issue is to apply for it wisely and to use it.

EVALUATING ANTIDRUG EFFORTS

That brings up the issue of testing. When Secretary Bowen was before this committee—the years run into one another. It may have been last year. It may have been the year before—I asked him what Health and Human Services knew about results on drug usage. And here again, we have had programs. I have worked in this field since 1968 when I helped bring the Densie House to Pennsylvania. They now have eight units in the State, I believe. It was an outgrowth of Daytop Village. But to this minute, nobody has tested the results. We put that in last year's drug bill, a specific mandate that there be the test results. I would urge you to pursue that.

I know how dedicated you men and women are in your Department to this objective, and you will have tremendous support from Congress on funding programs which succeed. But if you would direct your attention to those items, I'd be very grateful.

They have on the floor now a vote on the D.C. prisons that Senator Harkin and I have also——

Senator HARKIN. No; is that what that is?

Senator SPECTER. Yes.

Mayor Barry said yesterday that he needed a sense of the Congress resolution to help him get the prison bill.

Senator HARKIN. I can't believe it. [Laughter.]

Senator SPECTER. You can strike that from the record. [Laughter.]

Or you can associate Senator Specter with Senator Harkin's remarks, either way.

Thank you very much.

Senator HARKIN. Thank you, Senator Specter.

I have a couple of other areas to look into, but it looks like our time has run out. We will submit those in writing to you.

PROTECTION AND ADVOCACY GRANTS

One last thing I wanted to ask you is about the protection and advocacy program. It ensures that the rights of mentally ill patients in institutions are protected. In fiscal year 1987, these programs handled a total of 14,132 cases: 45 percent of those cases involved neglect; 23 percent involved abuse; and 32 percent involved other rights such as access to legal representation.

What is the justification for phasing over the protection and advocacy programs? They are down for an 18 percent cut, from $12.8 to $10.6 million. Have you identified any problems with these programs, or are they just unnecessary?

Dr. GOODWIN. Perhaps Dr. Judd could comment.

Dr. JUDD. The Protection and Advocacy Program is a responsibility of the National Institute of Mental Health, Mr. Chairman, and it has been in place for several years. The purpose of the program is to create, within the States, an independent group to monitor care of patients to make sure that they and their rights are protected.

This program, in our view, has been very successful up to this point. We have established technical assistance to the States to show them how to establish such programs, and we have provided formula grants for the States to set them up.

The model was that the Federal Government would serve as a catalyst to start this program, and that over time the States would begin to see how useful it was. At a certain point the Federal funds would be withdrawn—as the administration is proposing, and the States would then pick up the program funding.

We found in a survey of the States last year that there were some difficulties in some of the States, for the most part, all the States felt that these programs were effective and useful.

TOBACCO AND OTHER GATEWAY DRUGS

Senator HARKIN. Out of curiosity, how do you define a drug? What is a drug?

Dr. GOODWIN. Well, a drug, of course, generically is anything that has a biological effect on the body. We like to make the distinction between medications, which are prescribed drugs, and drugs more generally which often means drugs which are self-administered and often abused.

Senator HARKIN. Is tobacco a drug?

Dr. GOODWIN. Yes; nicotine, which is the most active component of tobacco, is a drug; yes it is a very powerfully reinforcing and very powerfully addictive drug.

Senator HARKIN. I just noticed in the high school survey, 3.4 percent were users of cocaine, but 29 percent were regular smokers, 66 percent regular drinkers. I assume alcohol is also a drug.

Dr. GOODWIN. Yes; now, of course, as Dr. Gordis mentioned, in the case of alcohol, the experimental use is to be distinguished from people who are drinking on a regular basis every month or every day. The decrease in daily drinkers is encouraging.

Senator HARKIN. It just seems to me that, first of all, you start smoking when you are young, it gives you a kind of a high.

Dr. GOODWIN. That's right.

Senator HARKIN. It gives you—what did you say? I forget that word you used.

Dr. GOODWIN. Reinforcement, reward?

Dr. SCHUSTER. Euphoria.

Senator HARKIN. Gateway. And then you drink, and you say, well, gee, this is not so bad, it makes me feel good. Well, if that is all right, then take the next step.

I am wondering if we just concentrate—this is something that we will continue not only this year but next year. We are putting too much into cocaine and the hard drugs, and we are not looking at the gateway drugs and really focusing on that aspect of our young people.

Dr. GOODWIN. I think you are right. There was a tendency to dismiss them. As I said, recent evidence from research—for example, that THC in cannabloids is very dangerous and sticks around for a long time, is gaining attention.

Also, I think, use of gateway drugs teaches kids substitutes for other ways of feeling good. When they are just developing their learning skills, just learning how to form relationships, how to invest in their school work, how to get interested in politics or whatever, if they find these short circuits, it really cuts into their development.

Senator HARKIN. I've got to go. Thank you. We will stand adjourned, but before I do I wanted to express Senator Inouye's pleasure and appreciation that Dr. Judd will be going to Hawaii next month to meet with the Native Hawaiians. Senator Inouye wanted me to pass it on to you.

Dr. JUDD. Thank you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. We will be in recess. I have to go do another vote. It will be about 15 minutes, and we'll be back for the next panel. Thank you, Dr. Goodwin. Sorry to rush off.

There will be some additional questions which we will submit to you for your response.

[A brief recess was taken.]

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

SLOW STATE BLOCK GRANT DRAWDOWN

Question. Congress created the Alcohol and Drug Treatment and Rehabilitation (ADTR) block grant in the 1986 drug bill to give states a "shot in the arm" to fight drug abuse. This grant money came on top of the funds states were receiving already in the Alcohol, Drug Abuse, and Mental Health Services block grant.

Of the $319 million we appropriated for the ADTR block grant in fiscal years 1987 and 1988, I understand that $132 million --41%--is still in the bank, not yet spent by the states; and seven states haven't even spent a penny of their 1988 funds yet.

Clearly, having two block grants for dealing with drugs was too cumbersome, so in the 1988 drug bill, Congress consolidated the two block grants into one grant, the Alcohol, Drug Abuse, and Mental Health Services (ADMS) block grant.

But even with one block grant, there seems to be a problem: Of the $805 million we appropriated in fiscal year 1989 for the ADMS block grant, less than $200,000 has been spent. Here we are, six months into the year already, and only 23% of these funds have been spent. We're still holding onto over $600 million.

I understand that some states must have their legislatures approve the spending, and that states have had some problems setting up programs to use these funds, but what is the Department doing to move this money into the pipeline?

Answer. ADAMHA contacted over thirty states that had drawn down less then 75% of their fiscal year ADTR Block Grant. Almost half of those states indicated that a state law requiring their legislature to be involved in the use of the funds is a factor affecting draw down. The Anti-Drug Abuse Act requires Legislative public hearings in all States as a condition of receipt of the funds.

States were told that the ADTR Block Grant funds were a "one time" resource and would require extensive coordination and consultation with all treatment providers. As a result, states carefully planned and implemented new programs to maximize the use of these scarce resources, and this took additional time.

ADAMHA is developing, in consultation with state directors and national organizations, a technical assistance plan to use the funds included in the 5% set-aside from the fiscal year 1988 ADMS block grant. A portion of the funds will be directed toward assisting the States in their overall administration of the block grant, including improved obligation and expenditure procedures.

SUPPLEMENTAL BLOCK GRANT FUNDING

Question. Legislation has been introduced to provide supplemental funds for this year for the block grant up to the authorized level. That would add another $700 million to the pot for this year. What is your estimate of how much the states will be able to use responsibly in the remaining months of this fiscal year?

Answer. ADAMHA has requested that Congress consider a Technical Amendment to the Anti-Drug Abuse Act of 1988 that would allow States an additional year to obligate the Fe ADMS Block Grant funds. We requested this amendment because of the significant changes in the legislation from previous years, the merging of the ADTR and ADMS Block Grants, and the delay in making the funds available. Without this Technical Amendment some states may have a difficult time obligating the current funds by September 30, 1989.

Supplemental funding at the level you are suggesting would have to be added to the current allotment--including a re-running of the formula. States would have to develop modified intended use plans, and some states would have to obtain legislative approval prior to the use of the funds. If an increase in funding were to be considered, even with advance notice to the states to allow them to properly plan for the use of funds, an additional year-- until September 30, 1990, would be needed to obligate the funds.

TECHNICAL ASSISTANCE FOR STATES

Question. I've heard several reasons why states haven't spent their FY 1988 drug funds, or even applied for their fiscal year 1989 drug funds: In many states, federal appropriations need to be approved by the state legislature before spending can begin.

Also, states hadn't planned for the Alcohol, Drug Treatment and Rehabilitation block grant funds, and they didn't have programs in place to use the money. On top of that, I understand that the grant award notices states received in fiscal year 1987 said, "Grantees should plan to use these funds to cover program costs through September of 1988." When states got more funds in fiscal year 1988, they were still sitting on their fiscal year 1987 funds. Other than sending states a letter of credit informing them of the funds available, what technical assistance has ADAMHA given States to identify effective methods or programs, so that they can get the ball rolling?

Answer. ADAMHA, in cooperation with the Bureau of Justice Assistance (BJA) and the Department of Education (DE), held a series of three seminars designed to provide State staff technical assistance on implementation of the Anti-Drug Abuse legislation. These seminars brought together over 500 state employees at three sites, for three and one-half days at each site, for directed technical assistance.

In addition to the coordination with BJA and DE, the last day of the three seminars was restricted to State ADM staff, and was aimed at presenting them with an in-depth review of the changes in the legislation and extensive discussions about possible problems

in implementation. These meetings allowed State staff access to each other and promoted cross-fertilization of concepts and solutions to problems related to the ADMS Block Grant.

ADAMHA staff have also met, at the request of state ADM Directors, with state staff on four separate occasions since the passage of the amendments of fiscal year 1988. These meetings brought together representatives of approximately 30 different states to discuss the ADMS Block Grant for fiscal year 1989. In these discussions, time was spent on how the legislation had changed and the new requirements/restrictions it contained, including the reduced obligation period.

The Anti-Drug Abuse Act of 1988 also included a 5% set-aside from the ADMS block grant, to provide among other things, technical assistance to States. We are currently developing a plan, in cooperation with state directors and national organizations, to implement this set-aside. Some of the funds expended under the TA plan will be to help States improve their administration of the block grant.

AVAILABILITY OF TREATMENT PERSONNEL

Question. The Committee has been informed that there aren't enough trained workers or treatment facilities to launch a full-scale effort against drugs, and that's one major reason states are slow to draw down the funds. Is this true?

Answer. Publicly funded treatment programs tell us that they are unable to recruit and retain qualified drug abuse workers because of the low pay in public programs versus that in private for profit programs. Any attempt to expand the treatment network would run into the limitations imposed by a lack of trained workers.

The drawdown of the block grants is a separate issue that we have addressed elsewhere. Essentially, use of the block grant funds in fiscal year 1989 has been slower than usual due to start up for new programs and due to explicit instructions given to states to use the money over a two-year period. The slow drawdown has not been linked to a lack of personnel or facilities.

Question. For the Office for Substance Abuse Prevention training programs in substance abuse, you have requested an increase from $5 million to $5.3 million. Under your request, how many substance abuse counselors can these programs train in FY 1990?

Answer. The Anti-Drug Abuse Act of 1988 specified that $5.0 million of appropriated funds be used for substance abuse clinical training programs and medical education training. The OSAP was provided $3.0 million to initiate a National Training System which will provide continuing education in alcohol and other drug abuse education courses for substance abuse counselors, health professionals, social workers, and community organization staff. The remaining $2.0 million provides support for an Alcohol/Drug Health Professions Education program jointly sponsored by NIAAA and

NIDA. This latter program will provide grants to health professions training institutions to train faculty to implement alcohol and drug abuse curriculum models.

The National Training system will begin operation in early FY 1990. OSAP anticipates that the system will initially focus on developing new packages, modifying existing manuals, training trainers who can in turn train staff on a nation-wide basis, and developing collaborative relationships with associations which can assist OSAP in creating a responsive training system. The system will subsequently be expanded to increase the scope of training topics as well as the number of persons trained. During the first year it is anticipated that between 3,000-5,000 Health Professionals (physicians, nurses, social workers, and substance abuse counselors) and community-based providers will be trained. Of this total, approximately 1,000 will be substance abuse counselors.

SCOPE OF THE DRUG PROBLEM

Question. Just pick up any newspaper, and you'll read about drug abuse. It seems to be in just about every community in the country. Is It?

Answer. While scientific data do not exist for every individual community in the country, the available data show that some level of drug abuse occurs in communities of all sizes. The 1985 National Household Survey on Drug Abuse found, for example, that among the household populations aged 18-25, 18.8 percent of those living in nonmetropolitan areas, 22.1 percent in large metropolitan areas, and 23.9 percent in small metropolitan areas had used marijuana during the month prior to interview. The 1988 High School Senior Survey shows similar findings by population density: Outside Standard Metropolitan Statistical Areas (SMSA) -- 14.3 percent past month marijuana use; large SMSA -- 19.4 percent; and other SMSA -- 19.3 percent. Followup data from the High School Survey show that in 1987 among young adults aged 19-22, the percent who had used marijuana in the past 30 days according to a more refined measure of population density was as follows: farm/country --16.6 percent; small town -- 21.0 percent, medium city -- 21.6 percent; large city -- 20.9 percent, and very large city -- 25.0 percent. Additionally, hospital emergency rooms located throughout the country report drug-abuse-related cases to the Drug Abuse Warning Network (DAWN). These data sources, together with reports from State and local epidemiologist, clearly indicate that drug abuse is pervasive throughout the country.

Question. What is the current estimate of how many addicts there are?

Answer. We estimate that there are 6.5 million individuals who are using drugs in such a way as to require a structured treatment program to deal with their problem.

Question. How many are in treatment?

Answer. Using the data generated by the NIDA/NIAAA 1987 census of drug abuse treatment programs (National Drug and Alcoholism Treatment Unit Survey), we estimate that about 270,000 individuals are in treatment at any given time.

Question. How many are on waiting lists?

Answer. The number of individuals on waiting lists is currently unknown.

Question. How many are being turned away from treatment, or even refused a place on waiting lists?

Answer. In a survey conducted by the U.S. Conference of Mayors in 1987, three out of four cities reported that drug abusers seeking treatment faced long waiting lists. The survey indicated that the waiting list could be as long as six months.

Question. How many treatment facilities are there?

Answer. There are approximately 5,200 identifiable drug abuse treatment programs throughout the Nation.

Question. How many facilities do we need now, or will we need in the next few years?

Answer. We probably need a total of 9,600 programs to substantially reduce the number of chronic drug abusers that form the core of the illicit drug market. Based on calculations from the National Drug and Alcohol Treatment Utilization Survey (NDATUS), approximately 5,792 programs for IV drug abusers (IVDAs) and 3,811 programs for other drug abusers will supply approximately 380,000 treatment slots for IVDAs and 250,000 other treatment slots. The highest priority should be to provide treatment to IV drug abusers in order to control the spread of AIDS both in and out of this population.

ALCOHOL AND DRUG ABUSE SURVEYS

Question. The Department supports two surveys about alcohol and drug abuse, a household survey every three years, and the annual survey of high school seniors. The household survey polls people starting with age 12. But we read in the papers about kids six and seven years old using and selling drugs. Should you include younger children in the 1990 household survey to get a better picture of abuse?

Answer. We should not include children under 12 in the survey, for several reasons. First of all, data from the 1985 survey suggest that illicit drug use is rare among children under 12. For example, only 2 percent of 12 year olds reported ever having tried marijuana. Of all marijuana users at any age, only 2.4 percent reported having used marijuana before age 12. Survey costs increase with each additional interview attempted, so the amount of additional information on the national drug abuse problem that we would obtain is not worth the expense. Furthermore, the

quality of data from children under 12 is likely to be poor, since we know that for younger children it will be more difficult to conduct interviews in private, since parents of younger children are more likely to remain in the room during the interview. Data quality will also be affected because younger children have more difficulty understanding the questions asked. Since the sampling plan, questionnaire, data collection procedures, and data analysis have all been designed based on a population 12 and older, any collection of drug abuse data on children under 12, if desired, should be done as a separate study designed specifically for that population.

Question. The 1988 survey of high school seniors showed that their drug use is at its lowest level in 10 years. That's good news about high school seniors, but what about dropouts? Research conducted by the National Institute on Drug Abuse found the rate of illicit drug use among 19-21 year old high school dropouts was 67% higher than for graduates of the same age. I'm not sure if drug use is really up or down. What is the feasibility of polling younger students, so that we get a more accurate picture of substance abuse among young people?

Answer. Currently, the National Household Survey on Drug Abuse provides an accurate picture of substance abuse among young people aged 12 and over. The National Survey also can be used to estimate drug use among those high school dropouts living in households. NIDA was one of the cosponsors of the 1987 National Adolescent Student Health Survey which collected information on alcohol and other drug use by eighth and tenth grade students. NIDA is also considering various options of obtaining data for younger students on an ongoing basis.

It is felt, however, that new methodologies are needed to better estimate rates of substance abuse among hard-to-reach or "hidden" populations, for example, dropouts. NIDA is beginning a multi-year study to examine the prevalence, incidence, and health and social consequences of drug abuse in "hidden" populations. Methods will be developed to collect data from these populations such as special questionnaires, survey instruments, and interviewing techniques.

Question. By concentrating our education efforts through the schools, are we missing the kids most likely to abuse drugs and alcohol? How can we get the message to them?

Answer. ADAMHA has long recognized the need to reach diverse groups in order to educate kids about the dangers of drug abuse. Thus, our efforts are targeted not only to schools but also to parents, community organizations and kids at high risk. NIDA conducts research oriented prevention activities while OSAP conducts activities that have education as their primary focus.

NIDA reaches at risk populations through radio and TV spots, printed flyers, and telephone hotline assistance. Most of NIDA's intervention research programs target children in junior high school, where school drop-out rates are very low. Many of these programs also include booster components at the high school level.

OSAP targets a wide range of intermediary organizations including religious institutions, fraternal and civic groups, youth-serving organizations such as the Boys and Girls Clubs, professional associations and organizations, the media, and federal and state agencies.

Among OSAP's products are a manual for community organizers and planners on how to design, implement and evaluate prevention projects. OSAP also publishes resource lists and pamphlets and works with the media and the entertainment industry to shape and transmit messages to high-risk youth through radio and TV spots, music videos, pamphlets, stickers, and other means.

In addition, OSAP provides assistance for national initiatives, for example: cooperation with various federal agencies including the Department of Housing and Urban Development to convey messages in high crime areas, the Department of Labor to convey messages in the workplace, and the Department of Justice to bring "McGruff" messages to elementary school children; and assistance for the "Just Say No" campaign, the Second National Conference on Alcohol Abuse and Alcoholism, and the Surgeon General's Conference on Drunk Driving.

OSAP's efforts through schools generally involve model programs aimed at students prior to school dropout age and they focus on high risk groups. For example, "It's Elementary," aims at reaching children of alcoholics and other drug abusers through the elementary school system. Many education activities at schools include special emphasis on communicating with those who are not very literate or who are otherwise disadvantaged.

In addition, OSAP operates the National Clearinghouse for Alcohol and Drug Information. Only about a third of the Clearinghouse's requests for information come from schools administrators, teachers and students.

Results are somewhat encouraging. For example, data from the High School senior survey and other sources indicates sharp reduction in the use of marijuana and some reduction in the use of cocaine. In addition, perceptions toward these drugs seem increasingly to be that they are harmful and socially unacceptable.

EVALUATION OF DRUG ABUSE TREATMENT

Question. We're spending millions of dollars each year on drug abuse treatment, prevention and research. I want to know if this money is being spent wisely, and what kind of evaluations the Department conducts to tell which treatments work, and which don't.

Your approach to preventing drug abuse is based on biomedical research about the effects of drugs on the brain and nervous system, rather than applied studies of how people actually use drugs, under the theory that if you explain to people that drugs are harmful, they won't want to use drugs.

But everybody knows that alcohol and nicotine are harmful, and yet we have enormous problems associated with drinking and smoking. My question is, how do you know this approach works? Have you been able to determine conclusively that educating people about the effects of drugs works? What evaluations have you done of this approach?

Answer. Prevention research funded by the National Institute on Drug Abuse goes well beyond biomedical research on the effects of drugs on the brain and nervous system. NIDA's prevention research encompasses epidemiological, etiological, clinical and evaluation research. Our research is designed to understand the nature and extent of drug abuse behaviors occurring in the United States through several surveillance systems: surveys of the general population (the High School Senior Survey conducted annually and the National Household Survey conducted triennially); the Drug Abuse Warning System which monitors visits to the medical care facilities across the United States such as emergency rooms medical examiners' offices; and CODAP which monitors admissions to drug abuse treatment programs in selected states. In addition, NIDA funds both cross-sectional and prospective, longitudinal studies that determine biological, social, environmental, and psychological factors associated with the initiation of drug abuse and the continuation of drug abuse.

Prevention interventions must include multiple models to target the specific needs of different groups of individuals and in any community several intervention approaches must be implemented to have the greatest effect on a population. In fact, the annual High School Senior Survey has shown that all types of prevention activities going on nationally have been having an effect on reducing the initial use of marijuana and cocaine. Recently, researchers from the University of Michigan reported that a ten year decline in marijuana use by high school seniors can be directly attributed to the dramatic increase in the perceptions of these seniors of the risks of physical and psychological harm associated with the use of marijuana and the increased perception of social disapproval of such use. Preliminary analysis of data from the most recent High School Senior Surveys indicate a similar relationship between perceived risk of harm and the decreased reported use of cocaine. These relationships will continue to be monitored annually and show the usefulness of such trend data which can explore these associations.

NIDA has been funding research to develop and evaluate specific intervention models as well as multiple model community interventions. As part of a NIDA supported program to evaluate various prevention intervention models, researchers at the State University of New York at Albany have conducted an analysis of 143 adolescent drug education programs and conclude that peer pressure is one of the most effective approaches. Of five prevention program modalities tested, those focussing on peer pressure were found to be the most effective in obtaining clinically significant effect sizes on all outcome measures including cigarettes, alcohol and other drugs.

In addition, the analysis revealed that a second program modality - Alternative programs - was particularly effective for high risk youth who were already having school problems, were using drugs to some degree, and who might be delinquent. Alternative programs are characterized by their focus upon providing youth community-valued and sanctioned activities that would be more appealing than drug use.

Research to examine the effectiveness of multiple component community-wide prevention interventions is also being conducted. In general these research studies include interventions that are channeled through the media, the schools and other community institutions that reach both children and parents.

Finally, NIDA has funded a prevention research center at the University of Kentucky which conducts prevention research in several areas including the biological basis of sensation seeking; developing media messages and other techniques to reach sensation seeking youth; and assessment of a school and community-based prevention education program designed by the Los Angeles Police Department called Drug Abuse Resistance Education (DARE). The center supports interaction across disciplines and as a result provides a comprehensive approach to research.

TAILORING TREATMENT TO THE NEED

Question. How do we get drug abusers and addicts into treatment?

Answer. They enter treatment via a number of channels. Some come to programs in desperation, voluntarily seeking help. Some are either directed or coerced into treatment by legal pressures (pending charges, court referral, conditions of probation, parole). Some are recruited by outreach workers in the community. The fact is that programs have no trouble filling available treatment slots, and there are waiting lists in many cities. If there were a sufficient expansion of treatment capacity, an aggressive outreach program could probably recruit about 30% of all addicts into treatment. In addition, actions taken by the courts and criminal justice system could bring still more addicts into treatment programs.

Question. No one treatment regimen is successful for everyone--how do we tailor treatment programs to different clients?

Answer. While treatment clients differ considerably in their needs, a relatively limited number of regimes is available, and treatment programs will have to have some flexibility if they are to be responsive. For example, a counseling program should also have medical services available on some basis. It may be necessary to provide antidepressant medication under the supervision of a psychiatrist, for some patients who also have mental illness. The needs of women, particularly those with small children (or about to give birth) should be addressed by making child care and prenatal/neonatal care available, since this is likely to have a direct bearing on the continued participation in and outcome of drug abuse treatment. Vocational training is also an important

component, coupled with interventions to increase employment readiness, since employment is a key part of the more stable lifestyle which drug abuse treatment seeks to bring about. The needs of drug abuse clients must be identified at intake, using such assessment tools as the Addiction Severity Index (ASI), which addresses multiple drug abuse related problems, to provide a better basis for tailoring treatment to clients.

DRUG ABUSE AMONG MINORITIES

Question. Overall, drug use seems to be diminishing--but what about within socioeconomic groups or minority populations?

Answer. Until data from the 1988 household survey become available in a few months, recent (since 1985) trends in drug use within socioeconomic groups and minority populations will be difficult to measure. NIDA's survey of high school seniors does provide data for some population subgroups. The high school survey shows the decline in drug use among seniors has occurred in all four geographic regions, in all three categories of population density (large metropolitan, small metropolitan, and nonmetropolitan), and for both sexes. The decline has also occurred among students planning to attend college as well as those not planning to go to college. Furthermore, followup studies on young adults previously sampled in the high school survey indicate recent declines in use in communities of all sizes, including farm/country areas, small towns, and very large cities.

The limited studies available concerning minority populations indicate that drug abuse continues to be a problem in general. Minority populations are decreasing their drug use but their overall level of recent and continuing drug use is higher than the national population of comparable age.

SUCCESSFUL TREATMENT METHODS

Question. What are some examples of successful treatment methods that minimize relapses among abusers?

Answer. Pharmacological treatments which are of value in preventing relapse include methadone, naltrexone, and psychoactive medications to treat psychiatric disorders which may make abusers more prone to relapse.

Methadone forestalls return to heroin use by preventing withdrawal sickness which can bring about relapse. Naltrexone is an opiate antagonist which blocks the effects of heroin and other opiates. It is useful in maintaining the resolve of otherwise motivated addicts to remain drug-free, by taking away a major incentive -- i.e., pleasure or relief from discomfort -- to use opiates. Research in treatment programs has shown that post-treatment outcomes are improved when clients take naltrexone. A major problem is that clients generally do not want to be on naltrexone, and some degree of motivation or pressure is needed.

Psychoactive medications are also useful in dealing with the high rates of co-morbidity among drug abusers and improving

outcomes. Research has shown that antidepressants may be useful in improving outcomes for cocaine abusers.

In non-pharmacological approaches, aftercare and relapse prevention are important aspects of treatment. Cognitive-behavioral approaches to relapse prevention involve development of skills to identify and deal effectively with the risks of relapse, including positive ways to manage stress, development of healthy relationships, how to avoid situations which place one at high risk of desire or pressure to use drugs, and development of a positive commitment to avoid return to drug use. Aftercare strategies may include such approaches as "clinically guided self-help", which seeks to build coping skills and strategies in the context of a group setting which has an built in commitment to abstinence. The group provides a context for learning about the risks of relapse, and ways in which such risks can be avoided or minimized, as well as a resource for the individual who is experiencing life stresses which threaten to precipitate a relapse. In addition to self-help groups, supervisory approaches such as urine testing of those clients under control of the criminal justice system or in employment situations where such testing is indicated may be of value in forestalling relapse.

ABUSE OF LEGAL DRUGS

Question. According to the 1988 high school senior survey, 3.4% of seniors are regular users of cocaine, but 29% are regular smokers and 66% are regular drinkers.Are we paying adequate attention to abuse of these legal drugs?

Answer. Yes, we are paying considerable attention to the abuse of these legal drugs.

Alcohol abuse among high school and college-aged youth is one particular concern. Persons aged 18-34 consume more alcohol than any other age group. Statistics indicate that accidents, many of which are alcohol-related, are the number one cause of death among youth and young adults. The academic and interpersonal problems, violence and crime, and economic losses related to alcohol abuse are immeasurable.

NIAAA is funding prevention studies to investigate the effects of parental and family influences, peer pressure, decision-making skills, and personality variables on the drinking habits of high school and college students. The effects of expectations and other cultural variables on drinking habits and changes in the drinking patterns of youth over time are the themes of other investigations. The efficacy of intervention efforts for pre-high children, especially children of alcoholics, also is being studied, as is the impact of parenting-skills on their children.

Prevention research is of such critical importance to the development of effective prevention programs that NIAAA has dedicated one of its National Alcohol Research Centers to such research. Using a public health systems model, the center at

Berkeley is focusing on a better understanding of the social and physical environments that influence individual behavior and problems related to alcohol abuse. In particular, peer influences on values and attitudes about drinking, the potential effects of television portrayals of alcohol beverage control agencies, and legal issues and legislation related to alcohol use are being studied.

A new initiative by the Institute invites studies that test the impact of norm-setting strategies in preventing alcohol use and abuse by youth and young adults. Research will examine norms set by parents and families, primary-care physicians, peer groups, education institutions, and community organizations.

Use of tobacco is a concern of NIDA. In some states the minimum age for legal purchase and use of tobacco products has been established. From a prevention and research perspective, activities differ depending on whether they are directed at adolescents or adults. The primary focus for adolescents is prevention; smoking cessation and prevention of relapse are the focus of adult programs.

According to the 1988 High School Senior Survey, 18 percent of respondents smoked cigarettes 20 or more times in the previous month. In the NIDA funded 1985 National Household Survey,3 percent of children aged 12-17 reported smoking a pack or more of cigarettes a day. In the Household Survey, 15 percent reported ever having used smokeless tobacco, while 3 percent reported using it once a week during the prior year. Significant declines in tobacco use are observed over time in both surveys.

Thus, the impact of media campaigns and other prevention programs can be seen in real declines in use. These programs have led to the creation of non-smoking environments and negative perceptions of the social and health consequences of smoking. However, attitudes about smokeless tobacco may not have changed; children tend to view it as safe. More information about the association of cancer with smokeless tobacco needs to be disseminated.

NIDA's Prevention Research Branch funds research on the prevention of the initiation of tobacco use. Longitudinal studies have identified tobacco and alcohol use as precursors to marijuana use, with ultimate progression to other illicit drugs. Thus, most NIDA prevention programs target tobacco and alcohol as well as other drugs. The use of alcohol and tobacco then become outcome measures of the effectiveness of such programs. Delaying the initiation of alcohol and tobacco into the early twenties when more mature attitudes about health risks may take hold is assumed to prevent use of not only alcohol and tobacco but illicit drugs as well.

Other NIDA groups fund research on the effectiveness of smoking cessation and relapse interventions. The thrust of these programs is to eliminate the use of tobacco. Other parts of NIDA are studying the abuse liability of nicotine.

NIDA efforts are part of a larger effort involving the National Cancer Institute and the National Heart, Lung and Blood Institute at the National Institutes of Health.

EXPENDITURES AGAINST ALCOHOL AND TOBACCO

Question. Please provide the subcommittee with figures on how much money is spent annually to combat alcohol and tobacco relative to illicit drugs, both for research, education, and prevention and treatment.

Answer. Many prevention activities generally promote healthy lifestyles and combat not only alcohol and tobacco use but also drug abuse and other unhealthy practices. Thus, it is difficult to produce reliable figures relating specifically to alcohol and tobacco. ADAMHA estimates that it spends $194 million annually to combat alcohol use and abuse. $73 million of that is by the Office for Substance Abuse Prevention for prevention and education activities designed at least in part to combat alcohol abuse. The balance is for research: an estimated $115 million on alcohol and an estimated $6 million on nicotine. In addition the Alcohol, Drug Abuse and Mental Health Services block grant provides over $400 million to States for substance abuse activities.

The Centers for Disease Control and the National Institutes of Health also conduct activities against alcohol and tobacco use and abuse. Like ADAMHA, it is difficult for them to parse out expenditures specifically for alcohol and tobacco because health promotion activities generally promote healthier lifestyles and thus are targeted against various unhealthy practices.

Clearly, federal expenditures represent only a small portion of the total national tab for preventing alcohol and tobacco abuse. For example, 1987 data from the National Drug and Alcoholism Treatment Unit Survey administered by ADAMHA indicates that, of at least $3 billion spent on alcohol and drug abuse treatment, over half--or $1.7 billion was spent on alcohol.

ALCOHOL ABUSE AMONG CHILDREN

Question. A recent poll of 8th and 10th graders revealed that 77% of 8th grade students have used alcohol--and 55% of those first tried it by age 6. The 1988 survey of high school seniors showed that 64% of them use alcohol regularly, and 35% have been on a drinking binge within the past two weeks. Is alcohol more of a threat than illegal drugs?--It's certainly more available to kids.

Answer. Both alcohol and illegal drugs constitute extraordinary hazards to the nation's youth. Debate about which is more harmful may be misleading, especially because abuse of each is often present in the same person and prevention and treatment strategies for the two are often similar or the same.

As you have indicated, the prevalence of alcohol abuse is greater than that of drug abuse. Alcohol-related accidents are the leading cause of death among adolescents. Accidents are also implicated in many cases of problems with schools, parents, and the

law enforcement system. Illegal drug abuse, on the other hand, brings its own special problems, including the threat of AIDS for those who share needles and the additional threat of running afoul of the law because of using or dealing drugs. Both are devastating to families, communities and work productivity.*

Question. The 1988 statistics on high school seniors look better than the 1987 data, but the drinking age has been raised to 21 for most of the country. Are we making progress, or is the apparent drop just a reflection of the higher drinking age?

Answer. The annual nationwide survey of high school seniors has shown a steady, though gradual decline in alcohol consumption since 1985. Research indicates that this is due, in part, to the higher minimum drinking age. Prior studies of the effect of changes in the legal age for drinking alcoholic beverages have indicated that the legal age affects the average age of initiating drinking, the percent of underage adolescents who drink illegally, and the rate of teenage driving under the influence of alcohol.

The high school senior survey does not contain such data for analysis but does contain information that indicates that factors other than legal age for drinking are affecting the decrease in alcohol between 1987 and 1988. Increasingly more seniors disapprove of drinking at all levels including trying one or two drinks. Significantly more seniors disapproved of drinking 4-5 drinks once or twice a week. Further, significantly more seniors reported in 1988 that their friends disapproved of their trying one or two drinks.

NIMH'S ROLE IN SERVICE DELIVERY

Question. In looking over the NIMH budget, it's hard to miss a trend of increases in research and corresponding cuts in services. Except for programs for the homeless, which the President pledged to fund at the authorized levels, services programs are cut. You are asking for cuts in clinical training, Community Support Demonstrations, and Protection and Advocacy for the mentally ill. At the same time, you are proposing an increase in research on mental illness. What is the point of your research on mental illness if it's not to enhance services to the mentally ill? Should NIMH have a leadership role in the area of service delivery, or would you prefer it be only a research institute?

Answer. Clearly, our aim is to do what we can to improve the health of those unfortunate millions of people who are suffering from mental illness, as well as from substance abuse disorders. NIMH, and this agency in general, has a critical role to play in that. The research of ADAMHA, like that of the National Institutes of Health, is essential to health services for various diseases. However, NIH does not fund the services system, nor is it ADAMHA's responsibility to do so.

If we are to succeed, we must develop new and better ways to prevent, diagnose, treat and rehabilitate those whom we serve. Such improvements are not likely unless they are based on sound research findings. Our responsibility includes not only conducting and supporting that research but also exerting leadership in

translating research results into improved services. But it is critical to remember that services can only be effective if they are based on knowledge based on research, not myths.

In addition to conducting and supporting basic biomedical and behavioral research, ADAMHA supports a broad array of activities focussing on services. As you know, comprehensive services are funded through block grants to the states. NIMH in particular also supports the following activities funded at $26.2 million in fiscal year 1988 and an estimated $29.7 million and $30.4 million in fiscal years 1989 and 1990 respectively:

- o Funding and conduct of mental health services research to provide new knowledge on:
  - Effective approaches to the organization and management of health service systems
  - Improved treatment approaches for underserved populations, (severely mentally ill adults, seriously emotionally disturbed children, the elderly, rural areas, minority populations)
  - New approaches to financing mental health services.
- o Funding and conduct of research and service demonstrations on effective treatment and rehabilitation approaches identified through services research.
- o Funding and conduct of State and community staff training in mental health administration and new service delivery approaches.
- o Provision of technical assistance and program consultation to State and community programs.
- o Funding and conduct of national data collection and evaluation studies to measure progress toward improving the quality of services for the severely mentally ill population.

PROTECTION AND ADVOCACY

Question. The Protection and Advocacy Program ensures that the rights of mentally ill patients in institutions are protected. In fiscal year 1987, these programs handled a total of 14,132 cases. 45% of those cases involved neglect, 23% involved abuse, and 32% involved other rights such as access to legal representation. What is the justification for "phasing over" the Protection and Advocacy programs? They are down for an 18% cut -- from $12.8 Million to 10.6 Million. Have you identified problems with these programs or are they unnecessary?

Answer. The Administration has not identified any problems with the Protection and Advocacy (P&A) Programs, nor do we feel that they are unnecessary. The justification for phasing over the P&A Programs is that the Administration has always believed that such activities are more the responsibility of the individual States. The funding which has been provided to date has enabled P&A systems to increase their staffs, to receive technical assistance from the NIMH to expand their program activities to serve mentally ill individuals, and to demonstrate their value to the States. Approximately half of the P&A systems now receive some amount of support from their State governments.
A gradual three year phase over from Federal support will allow the P&As to seek and obtain additional funding from State government and other private or charitable sources.

EVALUATION OF MENTAL HEALTH TREATMENT EFFECTIVENESS

Question. Last year, the House Government Operations Committee issued a report critical of ADAMHA and especially NIMH for spending less than 1% of its budget to evaluate which treatments are the most effective for different types of mentally ill people. What steps have you taken since then to increase treatment evaluations?

Answer. One way in which this is done in the mental health field is through what is known as services research. The National Institute of Mental Health has been encouraging research in a variety of areas, including this one, by developing and disseminating special grant announcements. For example, over the past six months, in the area of services research, the NIMH has seven such announcements which involve:

1. services for the homeless mentally ill;
2. services for children and adolescents;
3. services for persons with co-infection;
4. services for persons with HIV infection;
5. development of a center for research on self-help mental health services;
6. research by States to enhance their capacity for research; and
7. research conducted with a public-academic liaison.

For most of these announcements, the identification of which services are the most effective for different types of mentally ill persons is specified as an illustrative topic for the research.

This is not the only area in which the NIMH is reviewing the effectiveness of treatment modalities. In fact, the NIMH Report of the National Advisory Mental Health Council on a National Plan for Schizophrenia Research calls for a comprehensive program of treatment assessment research including the evaluation of drug treatment and the evaluation of psychosocial approaches. In particular, the Schizophrenia Research Branch has taken a lead in encouraging more research in the treatment of schizophrenia and is supporting a project entitled Treatment Strategies in

Schizophrenia. This broad based approach has the potential to assess the contributions of combined treatments as well as single forms of treatment. The study has just been competitively reviewed and renewed for another three years. The individual investigator-initiated program on the treatment of schizophrenia has shown an increase of 29% within the last year.

Finally, the NIMH Division of Clinical Research has established two Research Consortiums to examine the effectiveness of various treatment approaches to different psychiatric disorders. These include both the Psychotherapy and Rehabilitation Research Consortium (PRRC) and the Psychopharmacology Research Consortium (PRC).

Members of the PRRC, operating across intramural and extramural programs within the NIMH, along with consultants from the outside, will identify gaps in knowledge and impediments to research. NIMH will then encourage, facilitate, and improve the quality of services research on psychotherapy and rehabilitation. Efforts will also be made to disseminate to practitioners the existing knowledge about therapeutic approaches which are effective for specific disorders.

The PRC is now operating to coordinate research programs throughout all research Divisions of NIMH, both Intramural and Extramural. The Consortium provides interaction and communication among researchers in psychopharmacology, a field which is especially susceptible prone to the assessment of various modes of treatment effectiveness. This is being done through various mechanisms, including periodic meetings of NIMH research staff, organization of workshops on psychopharmacologic topics of public health significance, and subsequent recommendations for expanded research in priority areas, publication of the Psychopharmacology Bulletin, and planning and coordination of the Annual New Clinical Drug Evaluation Unit (NCDEU) Meeting.

SPENDING ON EVALUATION OF MENTAL HEALTH TREATMENT EFFECTIVENESS

Question. What proportion of ADAMHA's budget, and how much of the NIMH budget, is currently used for evaluations of treatment effectiveness?

Answer. NIMH, and ADAMHA in general, supports many projects evaluating the effectiveness of various treatment modalities for mental illness and substance abuse disorders. ADAMHA estimates that it is spending about 4% of its total budget on evaluation of treatment effectiveness in fiscal year 1989.

As I noted in the previous response, NIMH is supporting a variety of activities evaluating mental health treatment effectiveness. A description of key activities follows.

The Division of Biometry and Applied Sciences (DBAS), has released seven Program Announcements in the area of services research. They expect to spend approximately $8.9 million out of their regular research grant allocation; they also expect an

additional $7.9 million for services research from the block grant set-aside. This would be a total of $16.8 million in the DBAS.

The Division of Clinical Research (DCR) is the focus of the Schizophrenia Research Branch (SRB), as well as the both the Psychotherapy and Rehabilitation Research Consortium (PRRC) and the Psychopharmacology Research Consortium (PRC). The SRB is spending approximately $1.9 million on the Treatment Strategies in Schizophrenia collaborative project in FY 1989 alone, as well as proposing to spend $7 million for individual investigator initiated projects concerned with the treatment of schizophrenia.

The two consortiums do not require the same levels of funding, but have significant impact in the scientific community. For example, an advisory committee is currently being organized to provide input and consultation to the PRC from experts in academia, the pharmaceutical industry, and the Food and Drug Administration.

CHILDREN'S MENTAL HEALTH SERVICES

Question. In her 1982 book, Unclaimed Children, author Jane Knitzer reported that two-thirds of all children and youth who are severely emotionally disturbed do not receive the services they need. The Office of Technology Assessment confirmed those findings in a report last year.

To coordinate efforts in children's mental health services, NIMH launched the Child and Adolescent Service System Program in 1984. This program brings together all the different agencies that have responsibility for seriously emotionally disturbed children and gets them to coordinate services. It's working in 40 states.

Why have you proposed to cut funds for the Child and Adolescent Service System Program 27% when it seems to be working?

Answer. Within the FY 1990 budget, funding will allow for continuation of the existing grants which are still eligible to receive funds in FY 1990. Funds will also be available for new grants to States which will have finished two year Capacity Building grants funded in FY 1988. Any funds available beyond those above will be used for new research demonstration projects with a priority on homeless families and children. The decrease in funding of 27% reflects a de-emphasis on State-level grants which were directed at State-level coordination and strategy development.

Question. Under your proposed cut, how many of those currently served would lose services?

Answer. No current grantee will lose funding. CASSP is not, and has never been, a direct service program and therefore the number of children served by State Mental Health Authorities would not be directly affected.

AVAILABILITY OF MENTAL HEALTH TREATMENT PERSONNEL

Question. Under your budget, funding for NIMH clinical training is proposed to drop from $12.8 million to $8 million-- a

30% cut--as part of a 3-year phase-down. Yet I understand that there are still shortages of mental health specialists, especially in rural areas. Are there sufficient numbers of professionals available now to meet the needs of the seriously mentally ill?

Answer. The Administration intends to phase out this program, because its overall program objective--the increase of training capacity--has been accomplished. The Department intends, however, to focus its resources where the needs are most severe and persistent. For example, there are now shortages in mental health personnel for services to seriously mentally ill adults, children, elderly, and minorities in all disciplines. These shortages are even more acute in certain geographic areas, such as rural areas and inner cities. These shortages are precisely what the present clinical training program is addressing.

AN NIMH BUDGET OF $500 MILLION

Question. Dr. Judd, we have been receiving phone calls and correspondence about the need for supporting a total non-AIDS research budget level for NIMH of $500 million. Now we see that your current non-AIDS research budget request is $361,443,000. Have you heard of this $500 million figure?

Answer. Yes, we have heard the $500 million figure from the field. It would represent almost a $140 million increase in the President's proposed FY 90 NIMH non-AIDS research budget.

Question. Could you effectively spend that amount?

Answer. I can assure you that if, in this time of budgetary restraint, Congress in its wisdom were to allocate such an increase, it would be well spent. The additional funding would be used to intensify and accelerate major NIMH research initiatives concerning schizophrenia, the neurosciences, and child and adolescent disorders, among others, and to assure an ongoing, adequate supply of high-calibre researchers well-equipped to capitalize on the extraordinary growth of knowledge, technology, and opportunity in the study of mental illnesses.

Question. If so, for what would you use the increase?

Answer. Specifically, increasing the FY 90 NIMH non-AIDS research budget by approximately one-third would allow us to fund the following:

- 450 new and competing research program grants, permitting us to raise the award rate from a projected 19.8 percent to 32 percent.
- 13 new research centers focused intensively on high-priority areas of research, including the neurosciences, schizophrenia, Alzheimer's disease, suicide, and child and adolescent disorders.
- 80 more recipients of Research Scientist Development Awards, providing much-needed insurance that we will have outstanding research manpower to advance the future science of mental illness.
- A five-fold increase (from $1 million to $5 million) in support for research equipment to the field. Progress in

understanding mental disorders is predicated on having the high-tech tools that can unlock the secrets of molecular genetics, brain structure and function, and the electrochemical processes underlying emotion and thought.

- Double the number of research training stipends, which would help to both keep pace with the burgeoning field of brain science and to provide the knowledge needed to improve the diagnosis and treatment of mental disorders.

PLAN TO ATTACK SCHIZOPHRENIA AND OTHER SEVERE DISORDERS

Question. Dr. Judd, you are in the process of implementing a new combined National Plan for Research in Schizophrenia and Brain Disorders. Could you briefly tell us about it?

Answer. A scientific agenda for the next decade's research focused on the major mental illnesses has been developed by the National Advisory Mental Health Council in part in response to directives issued by the Congress.

The agenda is contained in two documents: the National Plan for Research on Schizophrenia, and the National Advisory Mental Health Council Report to Congress on the Decade of the Brain.

Together, the two Reports constitute the most intensive and comprehensive analysis ever conducted in this country of scientific needs and opportunities focused exclusively on the serious mental illnesses and involving both clinical and basic research strategies.

Even though the two research plans were developed under different mandates and involved different groups of scientists, their goals are overlapping. Taken together they outline the unprecedented opportunities that exist today for applying state-of-the-art clinical and basic research strategies to the study of serious mental disorders.

The NIMH has now combined the two plans into a single scientific attack on the major mental disorders, with the Schizophrenia Research Plan emphasizing the clinical investigations and the Decade of the Brain plan providing a complementary focus on basic research--each enhancing the other in a synergistic manner.

Never before has the NIMH, the scientific community, or the advocacy field possessed two such synergistically powerful instruments for the immediate and longer-term management of our research enterprise. The National Plan for Schizophrenia Research, with its high resolution focus on the scientific demands of a baffling and tragic group of disorders which will disable some 2 million Americans during the course of their lifetimes will draw increasingly on the yield of new information gained through a vastly expanded basic and clinical neuroscientific research program such as that mapped out in the Decade of the Brain report.

PROGRESS IN IMPLEMENTING THE PLAN

Question. What progress have you made in implementing it?

Answer. Neuroscience has made remarkable scientific progress in the past two decades. In fact, 90% of what we know about normal and abnormal brain function has been discovered in the past ten years. Implementation of the Combined National Plan is progressing at a good pace, although, of course, numerous unmet opportunities remain. Highlights of progress include:

- Recent NIMH funding of four Centers for Neuroscience and Schizophrenia (at Yale University, University of Maryland, University of California at Irvine and University of Colorado.) These Centers are for the support of integrated research relevant to schizophrenia. Clinical research has generated hypotheses implicating genetic, viral, developmental, neurochemical and other biological factors in schizophrenia; basic science research is now able to test some of these as well as generate additional testable hypotheses. The scientific opportunities offered by the integration of basic and clinical approaches to better understanding the clinical symptoms, pathophysiology, and etiology of schizophrenia appear to hold great promise.

- This concept of integrating basic and clinical neuroscience approaches into research on specific diagnostic categories is being expanded into a program of Centers for Neuroscience in Mental Illness, each Center to be devoted to the examination of a specific disorder. An announcement of this program will be issued to the field in 1989.

- The recent NIMH announcement of the Diagnostic Centers for Psychiatric Linkage Studies. The NIMH is launching a broad and multifaceted initiative to study the genetics of schizophrenia, bipolar disorder, and Alzheimer's disease. The primary goal of this component of the initiative is to establish a national resource of immortalized cell lines and psychiatric histories from reliably diagnosed patients and their key relatives. Funding for the Centers will be through the NIMH Cooperative Agreement Program wherein NIMH staff serve as active scientific collaborators with investigators at the awardee institutions. It is anticipated that nine Centers will be selected during FY 1989.

- The recent NIMH announcement of the Public Academic Liaison Program (PAL). This program was designed to strengthen research collaboration between research centers, especially academic research sites such as university medical centers, and the public centers responsible for the care of many severely ill patients (both children and adults), e.g., State hospital, community mental health center, or ambulatory program. Support under the PAL initiative will be through a variety of grant mechanisms. The initial receipt date for applications submitted in response to this

announcement was February 1, 1989, with an anticipated award date of December 1, 1989.

- The recommendations to establish a National Neural Circuitry Data Base has been advanced by the award of a contract to the National Academy of Sciences, effective in the last quarter of FY 1989. The goal of the NAS study will be to derive a consensus among experts regarding the requirements for and the definitions of the database. The recommendations resulting from this planning activity will be available for implementation in FY 1991.

FUNDING FOR THE PLAN

Question. What level of funding would you need in fiscal year 1990 to fully implement this plan?

Answer. Analyses of the relevant reports indicate that to fully implement the combined National Plan for Schizophrenia and Brain Research would cost $256,558,000.

Question. What is your budget level for the schizophrenia research plan in fiscal year 1989 and what is requested for fiscal year 1990 in this budget before us?

Answer. In the fiscal year 1989 budget, we estimated a total of $65,346,000 for research related to schizophrenia.

In fiscal year 1990, the NIMH is requesting $68,291,000 for research which is related to schizophrenia.

DECADE OF THE BRAIN REPORT

Question. Dr. Judd, the Committee has received your report on the Decade of the Brain. This report contains many recommendations and plans for increasing neuroscience research during the near future. What accomplishments you can point to over the last few years that lead you to believe there will soon be breakthroughs in some of these areas?

Answer: Neuroscience has made remarkable scientific progress since it began as an independent discipline in the 1970s. In fact, 90% of what we know about normal and abnormal brain function has been discovered during the last ten years. During this same period, the stage was set for further progress by the identification of the molecular and the submolecular units of the central nervous system, the development of major methodological and technological innovations, and the reconceptualization of the biological bases of the major mental illnesses.

Identification of the molecular and submolecular units of the central nervous system, which includes the brain, has enabled researchers to move beyond descriptions of "the cell" to analyses of discrete molecular actions which are the biological building blocks of behavior. Development of methodological and technological innovations has dramatically extended our ability to

observe the structure and functioning of the brain in living human subjects. Where the brain was once a static black box, it is now a dynamic model of blood flow, energy consumption, and structural variation. Reconceptualization of the biological bases of mental illness has focused attention on genetic predispositions, viral infections, and the interaction of the neuronal, hormonal and immunological systems.

Using molecular biology techniques and imaging technology, researchers are exploring the effect of individual psychotherapeutic drugs on specific target sites in the brain to more precisely identify sites and mechanisms of action for a wide range of pharmacotherapies. This information is being used to design new, more effective drugs, and to further our understanding of normal and abnormal brain processes.

Brain imaging techniques also make it possible to decipher the brain's activity in living, thinking, behaving subjects. Using these techniques, it is now possible to examine subjects in various behavioral states and determine which parts of the brain are involved, or deficient, during the performance of specific mental tasks. This strategy allows the comparison of brain activity in healthy and ill subjects to decipher biochemical signatures characterizing the diverse symptoms of individual mental illnesses.

For example, direct observations of the brain made possible by today's new imaging approaches reveal that, compared to the brains of normal subjects, the brains of patients with schizophrenia contain evidence of anatomical, physiological, and neurochemical abnormalities. Among these abnormalities are enlargement of the cavities of the brain containing cerebrospinal fluid, decreased activity of the frontal lobes during cognitive activity, and actual loss of brain substance.

In addition, the imaging technique called magnetic resonance imaging, or MRI, has provided evidence that in autistic children, one small region of the cerebellum is smaller than in normal children, a probable result of inadequate development of the brain during maturation. This region is known to control many of the behaviors affected by autism. Further studies will seek that critical point in brain maturation when a toxin, virus, or injury disturbs growth in the affected region.

One of the most consistent findings about major mental illnesses is that they run in families, suggesting they are inherited. The search for genetic markers and for the defective genes through which these illnesses are transmitted has proven to be a productive area of investigation and is currently one of the most active areas of neuroscience research.

Genetic studies and studies using genetic linkage methodologies have been most promising with manic-depressive illness, schizophrenia, and Alzheimer's disease. Investigators recently identified a link between schizophrenia and an abnormality on chromosome 5 in seven families with a high incidence of this disease. This finding follows reports last year from a study involving a very large family with high incidence of manic-

depressive illness. That study revealed an association between this disorder and an abnormality on chromosome 11.

These advances bring us to a position of confidence in predicting that avenues pursued by basic researchers in the 1990's will radically change diagnostic and therapeutic strategies in the 21st century.

PROGRESS IN IMPLEMENTING RECOMMENDATIONS IN THE REPORT

Question. What progress is being made in implementing the recommendations in this report?

Answer. Since formulation of The Decade of the Brain Report to Congress, the Neurosciences Research Branch of the National Institute of Mental Health has added one full time professional staff member to initiate a program of Centers for Neuroscience and Schizophrenia. This program now supports four centers designed to integrate basic and clinical neuroscience approaches into schizophrenia research.

This concept of integrating basic and clinical neuroscience approaches into research on specific diagnostic categories is being expanded into a program of Centers for Neuroscience in Mental Illness, each Center to be devoted to the examination of a specific disorder. An announcement of this program will be issued to the field in 1989.

Also ready for distribution to the field is a research announcement establishing Centers for Excellence in Molecular Neurobiology. These centers will seek to advance the application of significant new experimental strategies in molecular neurobiology to research on mental health problems.

In 1989, a program announcement was issued to the field in the area of Mathematical/Computational/Theoretical Neuroscience. An overwhelming response was received, and applications submitted in February of this year will be eligible for funding in December 1989.

The recommendation to establish a National Neural Circuitry Data Base has been advanced by the award of a contract to the National Academy of Sciences, effective in the last quarter of FY 1989. The goal of the NAS study will be to derive a consensus among experts regarding the requirements for and the definitions of the database. The recommendations resulting from this planning activity will be available for implementation in FY 1991.

Question. What level of funding would you need in fiscal year 1990 to fully implement this report?

Answer. In FY 1990, the full implementation of the recommendations contained in the Decade of the Brain Report would require an estimated $198.9 million budget within the National Institute of Mental Health. The FY 1990 budget request for this

activity is $143.5 million, an increase of $4.8 million, or 3.5% over the comparable amount for fiscal year 1989.

This amount of this budget request reflects the high priority we place on this effort among all of the exciting scientific areas competing for our limited resources.

CURRENT EXPENDITURE LEVEL FOR NEUROSCIENCES

Question. What are your expenditures for neuroscience research in fiscal year 1989, and what level of funding is requested in the budget request for fiscal year 1990?

Answer. In fiscal year 1989, estimated expenditures for neuroscience research are: Neuroscience Research Branch, $55.3 million, other related neuroscience research, $56.7 million, and intramural neuroscience research, $26.7 million for a total of $138.7 million.

In fiscal year 1990, the budget request for neuroscience research is: Neuroscience Research Branch, $56.6 million; other related neuroscience research, $59.0 million, and intramural neuroscience research, $27.9 million for a total of $143.5 million.

INSTITUTE OF MEDICINE STUDY OF CHILD/ADOLESCENT DISORDERS

Question. Dr. Judd, we understand that NIMH has asked the Institute of Medicine to assess the status of research on child mental disorders with specific recommendations about how the institute might provide vigorous leadership in clinical and basic research related to mental disorders of children and adolescents. Why have you placed such a high priority on this area of research? Are there unique problems in this area which have been inadequately addressed in the past?

Answer. The serious mental health disorders of children and adolescents affect at least 7.5 million of the 63 million children under age 18. While the direct and indirect costs of these disorders are difficult to estimate, they run into the billions. These disorders keep millions of children from ever reaching their potential. The consequences in personal suffering and failure to achieve economic and productive potential are enormous. Moreover, we know that some of these disorders are risk factors for later problems: alcohol and drug abuse, suicide, and antisocial behavior.

Of course, this is a very difficult area for research. One is dealing with the developing organism and so the research models applicable to adults sometimes do not apply. In the past, the research expertise was frequently lacking. However, advances in the techniques of diagnosis and classification, genetics, the neurosciences applicable to children, and developmental psychopathology have been great. The time is ripe. We need to move ahead in this long neglected but critically important area.

PURPOSE OF THE STUDY

Question. What is your overall goal in requesting such a study?

Answer. We wanted this study to document the great need for research in the child and adolescent disorders and also to point the way. It is my sense that the time is ripe. I wanted to know the specific priorities from a large group of experts.

When you are dealing with children, there are special problems in classifying disorders, in doing epidemiology, in using imaging techniques, and even in pursuing neurochemical studies and molecular genetics. For example, in diagnosing a disorder, one must frequently combine information from a child-patient with information gathered from a parent and teacher. In epidemiological field studies it may be difficult to get reliable and valid information about children under 10 or so and these techniques are just now being developed. Certain forms of imaging such as PET are accompanied by small doses of radiation and it is not ethical to allow this radiation to a developing organism unless the patient clearly benefits medically from the procedure as when PET is used diagnostically. Thus, PET for purely research purposes is not ethical for children. MRI has no radiation effect but requires that a patient remain perfectly still for a long time and this may be very difficult for children who are impaired. Nor can one ask a child to serve as a normal control by donating blood or spinal fluid.

My question was, can we really make progress here? The answer from the IOM was a resounding yes! They said move ahead. And they said move ahead in specific areas: epidemiology, assessment and treatment, prevention and services, and the neurosciences.

EXPENDITURES ON CHILD/ADOLESCENT DISORDERS

Question. How much are you spending for research on childhood mental disorders in fiscal year 1989, and how much is contained in the fiscal year 1990 budget for these activities?

Answer. In 1989, we are spending almost $89 million for research on childhood mental disorders. About 30% of this sum is spent directly on diagnosed disorders, that is, on children or adolescents who are autistic or depressed, or hyperactive or schizophrenic, etc. The other 70% is spent on research related to the childhood disorders. This related research covers prevention, antisocial and delinquent behavior, behavior and neuroscience research related to childhood disorders, and services research and demonstration programs.

In 1990, we will spend about $27 million directly on diagnosed disorders and about $67 million on related research, for a total of $94 million.

USE OF BLOCK GRANT FUNDS FOR DRUG ABUSE TREATMENT

Question. Up to now, states have been using a considerable amount of their block grant money for alcohol treatment. This

seems reasonable, because we have considerable evidence in the success of the Alcoholics Anonymous program that alcoholism lends itself to successful treatment. The 1988 drug bill places a much higher emphasis on drug abuse, concentrating on IV drug abuse. Do we have the same evidence about treating drug abuse that we do about treating alcohol abuse?

Answer. The evidence regarding treatment of drug abusers is similar for both drug and alcohol abuse, in that most persons with the disorder have complex treatment needs, enter treatment only after encountering multiple problems, and, when treated, tend to relapse a number of times before finally achieving long-term abstinence. Reliance on short-term detoxification in both drug and alcohol abuse is by itself not promising in terms of outcomes, but can be a useful first step in getting people into longer-term treatment. While some drug abusers are treated in alcohol programs (indeed, co-morbid drug and alcohol dependence is common), these tend not to be the intravenous drug abusers who are usually in programs which treat drug abuse only. The available kinds of treatment tend to differ for drug and alcohol abusers. For example, the drug abuse field currently has no equivalent of Antabuse, although it does have narcotic antagonists.

Question. How effective have programs aimed at IV and other drug abusers been in changing behavior and getting and keeping people off drugs?

Answer. Generally, the results of drug treatment are encouraging, but interpretation of treatment outcomes is complicated by the fact that many drug abusers will have multiple treatment episodes, including different types of treatment. It is not a matter of one short treatment and a cure, but rather like a chronic disease which is managed while the underlying problems receive attention. Among intravenous drug abusers, a wider range of treatments, notably methadone maintenance, is available. The management of drug dependence in methadone maintenance programs is exemplified by Dr. Kleber's study in which over 80 percent of clients remained abstinent for one year or more, although most relapsed after leaving treatment. We can say that methadone maintenance programs, outpatient drug-free, and residential drug-free programs all work even though relapse rates are relatively high.

Based on the latest outcome studies, we find that, for clients in treatment at least 90 days in various treatment modalities, between 61 and 77 percent had minimal or no drug use during the year after treatment. Studies such as Simpson and Sells' work with the Drug Abuse Reporting Program (DARP) have found that improvement among opiate addicts tends to include lifestyle changes, such as reduction of criminal involvement and improvement of employment participation. A more recent examination of methadone treatment by Ball has found that 71% of the methadone patients he studied had completely ceased intravenous drug abuse at the time he followed them up, although among a separate sample of treatment dropouts, the relapse rate was high, ranging from 29% during treatment to 82% at one year after leaving treatment. Ball also found adequate

methadone dosage to be important in preventing return to intravenous drug abuse during treatment.

Simpson has found that long-term outcomes among treated opiate abusers tend to be stable, and that after a period of several years, the percent not using opiates daily approaches 80%, while the percent totally abstinent from opiates and free from other major problems (heavy nonopiate use, heavy drinking, prolonged incarceration) to be 61%.

EVALUATION OF DRUG ABUSE TREATMENT

Question. How much of the fiscal year 1989 budget for drug abuse prevention and treatment is dedicated to evaluating the effectiveness of different methods? What portion of the budget for fiscal year 1990 is proposed for evaluations and effectiveness studies?

Answer. As required under Section 2039 of the Anti-Drug Abuse Act of 1988, a plan for the conduct of alcohol and drug abuse services research has been prepared and is being reviewed within the Department. In addition, the fiscal year 1990 budget includes $8.4 million for mental health and substance services research funded from the block grant set aside, or roughly the same amount set aside for such purposes in fiscal year 1989.

Drug abuse services research to be conducted with these set-aside funds includes cost/benefit studies of traditional as well as innovative drug abuse treatment and delivery programs and systems. Methodologies for including cost-accounting techniques in research on the quality and appropriateness of drug abuse treatment approaches will be developed, with the aim of analyzing real and potential cost offsets in various treatment programs.

Various drug abuse services research are ongoing. A description of key activities follows.

NIDA's Treatment Research Branch is concerned with a broad spectrum of scientific studies on drug abuse treatment. The primary objective of this research program is to evaluate and enhance the effectiveness of drug abuse treatment. Included in its research portfolios are controlled clinical trials to determine the safety and efficacy of psychotherapeutic, behavioral and pharmacologic interventions. Long-term outcome evaluation studies of treatment provided by different modalities or settings also are conducted. In addition, the development of new and enhancement of the effectiveness of existing interventions and treatment modalities is a high priority. Almost every grant or contract has an evaluation component. Approximately $65 million will be dedicated to supporting treatment research grants and contracts in fiscal year 1989.

NIDA's Prevention Research Branch supports studies of several intervention programs. Each includes an evaluation of the effectiveness of the intervention. In fiscal year 1989, $3.9 million will be spent on this effort.

OSAP has allocated approximately $1.5 million in fiscal year 1989 to evaluating the effectiveness of its High Risk Youth Grant and Community Assistance program efforts.

COLLECTION OF DATA ON SUBSTANCE ABUSE TREATMENT PROGRAMS

Question. What kind of data is being collected, and what are you doing to improve the collection of data for substance abuse treatment programs supported under the block grant? For instance, what is being done to keep track of treatment dropouts and treatment repeaters?

Answer. ADAMHA, through its institutes, has developed a comprehensive plan to improve the collection of substance abuse treatment data, in accordance with the data collection provisions of the Anti-Drug Abuse Act of 1988. Funds totalling $16 million from the fiscal year 1989 Alcohol, Drug Abuse, and Mental Health Services (ADMS) Block Grant were made available to NIAAA and to NIDA to carry out these efforts.

Among the activities planned by NIAAA and NIDA are the following:

- an expanded National Household Survey of Drug Abuse to improve national incidence and prevalence estimates;
- the conduct of household, high school, and special population studies, using Washington, D.C. as the targeted major metropolitan area;
- the expansion and enhancement of the Drug Abuse Warning Network (DAWN) to collect additional information on individuals admitted to hospital emergency rooms and deaths reported to medical examiners as a result of alcohol and drug abuse;
- the expansion and annual conduct of a major national survey to acquire information on the number and variety of public and private treatment programs--including patient slots, services, demographics, funding, and staffing);
- the development and implementation, with states, of a substance abuse treatment client minimum data set--including the establishment of a grant program from the set-aside monies to assist States in these efforts;
- the improvement and expansion of the existing National High School Survey to measure the extent of substance abuse among a broader age spectrum of school students; and
- the conduct of special studies of populations at high risk of alcohol and drug abuse, such as school dropouts, college students, and those individuals who do not reside in traditional households. The conduct of studies

involving the causes and impact of treatment dropouts and recidivism are matters that require complex research protocols. Specific efforts in this area are being conducted through NIDA research grant announcements, with a high-priority given to patient recruitment, retention, and relapse studies, especially among IV drug abusers. As findings from these efforts become available, such information will be disseminated to the federal, state and treatment provider levels.

EVALUATION OF ALCOHOL AND DRUG ABUSE TREATMENT PROGRAMS

Question. Section 1922 of the Anti-Drug Abuse Act of 1988 requires the NIAAA and NIDA to "evaluate alcohol and drug abuse treatment programs to determine the quality and appropriateness of various forms of treatment," and to submit a plan within six months of the date of enactment. That's this May. What is the status of the health services research plan? When can we expect to see it?

Answer. The health services research plans, required under Section 1922 of the Anti-Drug Abuse Act of 1988, were developed separately by NIDA and NIAAA. These plans are described in the report to Congress which is currently being reviewed within ADAMHA prior to submission to the Public Health Service and the Office of the Secretary for transmittal to Congress.

The report is composed of two parts: (a) the drug abuse services research plan, developed by NIDA and the alcohol services research plan, developed by NIAAA. These plans are an important step in the process of monitoring and managing an integrated research effort to document the effectiveness, quality, appropriateness, and costs of alternative drug abuse and alcohol abuse treatment. We expect the plan to be released to the Office of the Secretary within the month, and to be transmitted to Congress soon.

Question. What is the status of states' implementation of the new requirement that they provide independent peer review of subcontractors under the block grant to assess the quality and appropriateness of treatment services?

Answer. All applications for the ADMS funds have contained the Governor's assurance that the state will comply with this requirement. The states are not required to report on their progress in implementing the provision. States have requested information about the intent of the legislation, for example, what was meant by "periodic", "independent" and "peer review". States also have asked for input as to whether their current activities qualify in meeting this requirement. States have not expressed strong concern over their ability to meet this requirement.

RESPONSIBILITIES OF NIDA

Question. The National Institute on Drug Abuse was created by the Drug Abuse Treatment Office and Treatment Act of 1972--Public Law 92-255. The Senate report accompanying that legislation (Senate Report 92-509, page 18) says that NIDA was created to

"conduct all drug abuse prevention, training, treatment, rehabilitation, and research programs." The Conference Report contained the Senate provision (House Report 92-775).

As originally conceived, NIDA's mission focussed on treatment and prevention as well as research. I understand that when funding was transferred to the state block grant, it put a great deal of responsibility on the states for carrying out prevention and treatment programs; but isn't there still a federal role? Shouldn't you be providing leadership in these areas?

Answer. ADAMHA has historically had an important role to play in service delivery and education. Indeed, ADAMHA has a mandate to provide leadership in the form of policy guidance and technical assistance to the Nation's mental health, alcohol, and drug abuse service providers and related systems, including the educational sector.

Within an increasingly sophisticated and competitive health services arena, our credibility and success as a leadership agency is hinged on the quality and relevance of our research base. It is essential that we possess solid, empirically-derived information that we can draw upon in formulating and policy and in offering technical assistance to the States as they work to enhance the clinical service systems and prevention programs administered under their auspices. I am confident, as well, that a dynamic and productive scientific enterprise that is understood by the public to be relevant to the problems at hand, encourages individuals and community groups not to turn away from the difficult problems of mental illness and substance abuse; that research encourages hope and positive attitudes so necessary to the implementation of effective treatment and prevention programs.

A more immediate role assumed by ADAMHA in providing national leadership germane to the treatment and prevention of alcoholism and other forms of drug abuse is carried out by our Office for Substance Abuse Prevention (OSAP), especially through its demonstration authorities. When it was established, OSAP's responsibilities included operation of the National Clearinghouse for Alcohol and Drug Information and its related activities, community technical assistance contracts, and a grant program for high risk youth. Under the 1988 expansion of its mission, OSAP is responsible also for developing and implementing a model demonstration program for drug addicted pregnant women, post partum women and their infants; a state-coordinated community youth activity program; a national training system for substance abuse prevention and treatment; and a community-wide grant program to develop long-term strategies for the prevention of substance abuse. The aim is to establish a productive, overall program that will address the alcohol and other drug abuse prevention needs of the Nation.

Question. What is your view of NIDA's and ADAMHA's responsibility for leading prevention and treatment of substance abuse?

Answer. Although the block grant is, and should remain, the major source of federal support for substance abuse prevention programs, ADAMHA through its Office for Substance Abuse Prevention still provides categorical funding for community based prevention programs, especially innovative approaches. In the area of treatment, we see the appropriate federal role to continue to fund services through the block grant mechanism. NIDA's special role is to: develop and demonstrate new cost effective treatment approaches; provide opportunities for treatment practitioners and researchers to exchange information; encourage innovation and improvement in treatment quality; collect and interpret data on the way the treatment system operates and performs; and stimulate communities to support the development of treatment programs.

RESEARCH AND SERVICES

Question. Dr. Goodwin, you have discussed the similarities between your research and the research conducted by NIH. I'd like your opinion on one program at NIH, which combines health research with service delivery. The National Cancer Institute's Community Clinical Oncology Program conducts cancer treatment and research. Patients in the research protocols receive state-of-the-art cancer treatment. At the same time, the NCI benefits from cost-effective cancer research. To me, this initiative is especially prudent in times of tight budgets.

The marriage of services and research seems to be right in line with ADAMHA's dual service-research mission. What is the feasibility of ADAMHA collecting data through services for use in research and policy decisions in the way that NCI does?

Answer. In its research demonstration programs, the National Institute on Drug Abuse has organized its research and service delivery in a manner similar to that employed by the National Cancer Institute in its cancer control program. For example, in NIDA's outreach demonstration research program, an extensive network of service delivery systems has been implemented to prevent the spread of HIV infection among intravenous drug abusers and their sexual partners. Service delivery systems have been established at more than sixty sites across the country, with the capacity to reach a minimum of 10,000 individuals annually. As in the NCI cancer control program, the service delivery activity is joined with a program of evaluative research to determine the effectiveness of these strategies in preventing the spread of HIV. The data gathered from this program also contribute to NIDA's epidemiological research program, providing the most comprehensive source of information on the drug use and sexual practices of intravenous drug abusers who are not in drug abuse treatment.

Similarly, NIDA has recently initiated a treatment demonstration research program. The first applications under this program are currently under review, and the first grant awards will be made later this fiscal year. This program will expand the availability of drug abuse treatment which is currently in short supply using the most promising strategies that have emerged from previous research. Evaluative research on treatment methods

employed will simultaneously lead to the refinement of existing treatment methods and the development of new methods.

In addition to these demonstration efforts, NIDA also currently collects data on drug abuse treatment facilities, and a major new initiative to systematically collect data on clients in treatment and the services provided will be undertaken beginning in fiscal year 1990.

ADAMHA'S AIDS INITIATIVES

Question. The National Research Council (NRC) of the National Academy of Sciences issued a report recently on AIDS, drug abuse, and sexual behavior. The report calls for research on needle exchange programs, especially in light of research data from other countries indicating success in reducing the rates of new HIV infections while not increasing or promoting drug use. How effective have programs aimed at IV and other drug abusers been in preventing the spread of infection, and what is ADAMHA doing to collect information on these programs?

Answer. In 1987, NIDA developed and implemented a nationwide AIDS demonstration research prevention program targeted to intravenous drug users who are not in treatment, and to their sexual partners. At this time NIDA has funded 41 projects establishing 63 demonstration research sites. Virtually all projects are funded for a three year period and all are now in the process of gathering data and evaluating the efficacy of the different preventive interventions initiated.

All projects make use of certain core elements to guarantee the collection of data in a standardized format that will allow the rigorous evaluation of preventive strategies.

(a) A standardized structured interview schedule is administered to all intravenous drug users and sexual partners receiving preventive interventions. The interview schedule explores risk-taking behaviors associated with drug use and with sexual behaviors. HIV testing is made available.

(b) The vast majority of grant-funded projects - and all those funded within the past 18 months - make use of a clinical trials paradigm. As a part of NIDA's research, special effort is made to gather sufficiently large samples of blacks, Hispanics and whites, and of females and males, to guarantee an understanding of the efficacy of different interventions with those populations.

(c) Each project is developing a detailed protocol describing the nature and functioning of the preventive interventions in use. Thus, those interventions found effective can be made available to other comparable communities for their use.

(d) All projects are making use, or will make use, of a standardized structured interview schedule administered to all individuals at six months followup after implementation of the interventions. Again, the interview schedule assesses risk-taking behaviors to learn whether or not there has been any diminution in risk-taking behaviors in the groups exposed to preventive interventions, and whether the groups exposed to innovative preventive interventions show greater diminution in risk-taking than those exposed to standard interventions. In addition, because all individuals are offered HIV testing at intake and followup, rates of seropositivity can also be studied and compared between groups.

One example of a successful intervention is in San Francisco. A study conducted between 1986 and 1988 has demonstrated that street-based education of IVDAs continues to show important improvement in injection-associated HIV transmission risk. Furthermore, the changes in needle hygiene appear to have lowered the overall risk of HIV infection among IVDAs in San Francisco, and appears to be a factor in attenuating the spread of HIV.

AIDS CLINICAL TRIALS

Question. The NRC recommended funding "randomized field experiments" for evaluating new interventions. These clinical trials of AIDS prevention projects comparing one community's response against another are essential to improve our knowledge of how to prevent AIDS transmission through changing behavior. Does ADAMHA's budget include funding for such an effort? Is this kind of effort feasible at this time?

Answer. In FY 1989 ADAMHA is spending $45 million for AIDS demonstration research prevention activities. Funded activities include intervention research on behavioral and psychosocial factors involved in the spread of HIV infection, and studies that stress intervention research on linkages between alcohol abuse and unsafe sex practices.

Clinical trials of AIDS prevention projects are feasible; in fact, funds for such trials are being requested in the fiscal year 1991 budget. ADAMHA is conducting some community prevention trials. The Agency continues to emphasize the importance of such trials and would welcome applications to develop, implement and evaluate population specific interventions designed to change high-risk, AIDS-related behaviors. In order to reliably evaluate the effectiveness of various intervention strategies, large studies employing standard measurements are needed.

COMMUNITY BASED PREVENTION PROGRAMS

Question. What research is ADAMHA conducting to evaluate the effectiveness of community-based prevention programs?

Answer. In the last two years ADAMHA has initiated about 40 research demonstration projects that measure the efficacy of preventive interventions targeted to intravenous drug users who are not in treatment and to their sexual partners. All persons exposed to preventive interventions receive standardized structured interview schedules so that we can assess the nature and extent of their risk-taking behavior as well as demographics and other background characteristics. HIV testing is available on a voluntary basis and forms another source of data.

At six-month follow up after the intervention, all individuals are contacted for follow up interviews and the opportunity for a second HIV test. Typically, studies are organized in a clinical trials paradigm to allow comparison of innovative to standard interventions on the basis of a random assignment of individuals or communities to each. All interventions will be described in detail to facilitate the transfer of successful technologies to other communities.

Prevention strategies in ADAMHA have involved gay males, intravenous drug abusers, and adolescents at risk. Results indicate that certain groups are changing their behavior. For example, a study of gay males in New York City indicates a dramatic increase in the use of condoms and a low rate of unprotected anal intercourse. In that study, the incidence of infection among seronegative men was reduced to 2.3% in 1986 and 0.4% in 1987.

COUNSELING AND TESTING OF IV DRUG ABUSERS

Question. How does NIDA coordinate counseling and testing of IV drug abusers with CDC's activities of the same nature?

Answer. CDC has funded HIV testing and counseling in drug abuse treatment programs in 20 States. That testing is available to NIDA's outreach demonstration research grants and contracts as well as NIDA's HIV seroprevalence monitoring program. With specific regard to the outreach demonstration research program, NIDA and CDC schedule joint site visits and hold cooperative regional conferences to assure cooperation and a sharing of information. In addition, NIDA provides training opportunities to staff of State health departments, again acting in conjunction with CDC, to provide support for education in activities relating to intravenous drug users and their sexual partners. NIDA plans a further expansion of its training program in conjunction with CDC to develop still closer coordination between State drug abuse agencies and State health departments and to increase numbers of health service workers in training.

In association with NIDA's seroprevalence study, CDC has transferred funds to NIDA to support comprehensive testing and counseling without duplication of effort or services. CDC and NIDA staff routinely discuss testing and counseling services in communities participating in the seroprevalence study, and NIDA submits quarterly reports to CDC regarding services provided. To further assure cooperation, NIDA and CDC meet regularly as a part of scheduled monthly meetings of the PHS Addiction and Behavior Subgroup.

Question. How does the current availability of services for drug treatment affect HIV prevention efforts? Are interim measures, including needle exchange, bleach, and "no frills" methadone programs, effective in preventing the spread of the HIV infection?

Answer: The current limited availability of services relative to need creates significant difficulty for HIV prevention efforts. The most effective strategy for changing risk-taking behaviors related to intravenous drug use is through involvement in long-term drug abuse treatment. A host of studies have established a relationship between length of time in treatment and change in drug using behavior. Thus a key element in AIDS prevention programs working with intravenous drug users out of treatment is to get those users into treatment. The absence of treatment slots in many communities obviously frustrates a use of that strategy.

We cannot yet speak to the efficacy of the various interim measures available to contain the spread of HIV infection. Study does indicate that, in those communities in which bleach is made available, there is a marked increase in the use of bleach and understanding of its capacity to halt infection. In the wake of a lethal disease that has already claimed more than 46,000 lives and that is growing most rapidly among IV drug users, their sexual partners and offspring, an understandable urgency is felt about exploring all reasonable strategies that can be seen as having the potential to contain the spread of disease through a community.

NIDA and the FDA have recently proposed revisions in the conditions for the use of methadone in the maintenance treatment of narcotic addicts which would allow programs to provide minimum service (interim) maintenance treatment to patients awaiting placement in comprehensive maintenance treatment and require programs to provide counseling on avoidance of HIV transmission. These requirements are being proposed in response to the HIV epidemic and are intended to allow more narcotic addicts into treatment more quickly, thereby decreasing the incidence of intravenous drug abuse and the transmission of HIV. A recent study conducted by a methadone treatment program showed that minimum service maintenance treatment, similar to the interim maintenance treatment provided for in the proposal, significantly reduced needle use among the program's patients. FDA and NIDA recognize that availability of funds, facilities, and trained personnel affects the immediate expansion of narcotic treatment programs. The agencies are also aware of the waiting lists for methadone treatment that are currently present in a number of cities across the nation. The changes proposed by FDA and NIDA will permit programs to provide interim maintenance treatment to help alleviate the human suffering of addicted individuals and reduce the abuse of IV drugs.

NIMH AIDS CLINICAL TRAINING

Question. The Committee understands that recently the National Institute of Mental Health issued a Request for Applications (RFA) for the AIDS clinical training program. This program was designed to help train health and mental health care workers about the psychological and mental health issues attendant to HIV infection. Under the new RFA, however, the individual NIMH recipient programs will be placed under the administration and direction of a primary care provider program otherwise funded and administered by the Health Resources and Services Administration (HRSA). How does this new approach address the unique needs of mental health providers working in AIDS?

Answer. The NIMH AIDS clinical training program, developed in 1986 to train health and mental health care providers in the neuropsychiatric and psychosocial aspects of HIV infection and AIDS, has been successful in developing model curricula and training approaches. Over the past three years, 21 contractors have developed and tested a broad range of training materials, and have trained over 20,000 health and mental health care workers. These successful training approaches should now be disseminated in a systematic way across the nation.

HRSA funds 13 Education and Training Centers (ETCs), each of which is responsible for AIDS health care worker education in a region of the country. Integrating training on mental health aspects of HIV infection into the ongoing health training of the ETCs will provide a regional approach for the comprehensive AIDS education of the nation's health and mental health care workers. To achieve this, NIMH has issued a Request for Applications (RFA) to incorporate AIDS mental health education into ongoing HRSA training efforts. With this new direction, NIMH will maintain responsibility for technical assistance and monitoring of the mental health component of AIDS training.

The recently issued RFA on "Expansion of Grants to Support Health Resources and Services Administration Sponsored Education and Training Centers to Include Training on the Mental Health Aspects of AIDS" will enhance the nations' AIDS training capability through the integration of training in mental health aspects of AIDS into the 13 regional HRSA ETCs. The RFA specifies that applicant ETCs are encouraged to work with an entity with demonstrated mental health expertise to provide specialized mental health skill and knowledge for the project. Application requirements include: a specific plan of how the applicants will integrate AIDS mental health training with the HRSA ETCs; a plan to incorporate into the curriculum emerging research knowledge of neuropsychiatric and psychosocial aspects of AIDS; a plan to train providers in prevention strategies and risk reduction; training for providers on counseling pre- and post- HIV antibody testing; and training to recognize, treat or refer individuals with psychiatric and neuropsychiatric complications of HIV infection.

Question. Aren't there special needs and concerns in the mental health arena that might not be met by a program that combines mental health and medical care?

Answer. Mental health training will be conducted by mental health professionals with expertise in AIDS and psychosocial and neuropsychiatric aspects of AIDS. In fact, the newly-issued Request for Applications (RFA) has highlighted special needs and concerns in the mental health arena that have not been met adequately such as training of health and mental health personnel who serve the mentally ill. At the same time, the RFA emphasizes a broad range of needs for mental health training, including a focus on special needs of subgroups, incorporating emerging research knowledge of neuropsychiatric and psychosocial aspects of AIDS, prevention and risk reduction strategies, training on counseling pre- and post- HIV antibody testing, and training to recognize, treat, or refer individuals with psychiatric and neuropsychiatric complications of HIV infection.

Question. What are NIMH's plans for continuing AIDS clinical training? Does the Institute plan to discontinue this program or conduct it under an agreement with HRSA?

Answer. NIMH plans to continue the AIDS clinical training efforts at the same level in FY 1990. The Institute has no plans to discontinue this program. NIMH collaborates with HRSA to integrate mental health training into ongoing AIDS training of health care providers. However, there is no formal agreement in this regard between NIMH and HRSA.

PREGNANT DRUG ADDICTS

Question. A recent study found that at least 11% of pregnant women in both urban and rural areas had used illegal drugs in pregnancy. The study suggested that 375,000 newborns each year face health damage due to their mothers' drug abuse. Yet pregnant women are often turned away by addiction treatment programs. What is the status of the demonstration grants administered by the Office for Substance Abuse Prevention for pregnant addicts and their infants? How many demonstrations are you funding, and when will findings be available?

Answer. After a review of the literature and extensive consultation with the leading practitioners, professional organizations and researchers in this field, a grant announcement was developed by the Office for Substance Abuse Prevention (OSAP). The announcement invited proposals for the creation of service demonstrations projects for substance abusing pregnant and post partum women and their infants. Six regional workshops were also held to further inform the field about the issues leading to the announcement, to provide insight as to the types of projects that were eligible, and to provide technical assistance with grant writing.

Proposals are due on May 15. Before the end of the fiscal year, OSAP anticipates funding approximately 20 projects. Data on the implementation of these programs (process evaluation) will be available on a regular basis throughout the grant period (3-5 years). Initial outcome data will start to be available by

October, 1990 and increase in quantity, reliability and validity over the following 2-4 years.

COORDINATION OF SERVICES FOR HANDICAPPED CHILDREN

Question. As Chairman of the Handicapped Subcommittee, I have heard about many problems in providing appropriate special education services to children with serious emotional disturbances. We need more research on effective services for these kids, and we need more teachers trained to work with them. This seems to me to be an area where the NIMH and the Department of Education should be working together closely. Is the NIMH working with the Department of Education to develop effective programs in schools?

Answer. The NIMH co-funds two Research and Training Centers with the National Institute on Disability and Rehabilitation Research (NIDRR) within the Department of Education. These Centers focus on improving services for seriously emotionally disturbed children and their families; they are located at Portland State University in Portland, Oregon and at the Florida Mental Health Institute at the University of South Florida in Tampa, Florida. Both Centers have conducted research related to the interface of mental health and education.

The Portland R&T Center has focused on both transition issues (i.e., aging-out of the child system as well as moving between residential and community-based care) and parent/professional collaboration.

The Florida R&T Center has conducted a five-year longitudinal study of over 900 children identified as seriously emotionally disturbed by either the mental health or public school systems in five States across the country. The Center is collecting data in order to study (1) how service system entry points do or do not effect the types of treatment, education and other support services received by these children, as well as (2) the ultimate impact these services have on their ability to function in community-based settings over time.

NIMH and NIDRR have also funded an additional study at Bank Street College under Dr. Jane Knitzer, entitled "Children's Mental Health and the Schools: A National Study." The purpose of the study is to identify: (1) promising school-based intervention programs for children who are already identified as seriously disturbed, and (2) those programs aimed at preventing future disturbance. The study, which will be completed in the fall of 1989, will identify programs in which schools work together with mental health or other agencies, strategies to overcome fiscal and administrative barriers, and promising State and federal policy initiatives.

Question. Does NIMH have expertise that would be helpful to the Department of Education in establishing programs to meet the needs of children with serious emotional disturbances?

Answer. Yes, school mental health programs have always been a part of NIMH's interests. Through the Child and Adolescent Service System Program (CASSP), an NIMH grant program encourages and facilitates the blending of mental health and education resources and expertise in the development of services for seriously emotionally disturbed children and youth. Institute personnel are participating in a Department of Education study to better define the concept of serious emotional or behavioral disturbance.

WOMEN'S HEALTH

Question. The Public Health Service established a Task force on Women's Health in 1983. The task force pointed out that gender plays an important role in the causes, effects, and treatment of alcohol, drug abuse, and mental illness, but the nature and extent of that role is poorly understood. What has ADAMHA done to look at women as a group?

Answer. ADAMHA has emphasized women's health in a number of important ways. A description of some key ones follows.

Research is being conducted on alcohol problems among women to determine fetal alcohol effects and the physiological consequences of women's drinking. Studies on fetal alcohol effects include determining the periods during pregnancy that impose the greatest risk; the levels and patterns of drinking that impose risk; and factors that may interact with alcohol exposure to increase or decrease that risk. Research on the physiological effects of drinking include longitudinal studies to determine patterns, antecedents and consequences of women's drinking; the role of alcohol abuse in the development of osteoporosis; and the effects of alcohol abuse on reproductive functions.

The effects of opiate and cocaine abuse on the outcome of pregnancies is another area of concern. Evidence suggests increasing drug abuse among pregnant women. A 1988 survey of 36 hospitals indicated drug abuse among eleven percent of pregnant women, including rich and poor, urban and rural. Few such women receive perinatal care. Providers are often ill equipped to treat pregnancy and drug abuse at the same time. Studies underway focus on developing components of comprehensive service for such women while, at the same time, designing, implementing and evaluating community outreach programs designed to eliminate barriers to treatment.

Studies that relate drug abuse to violence, women in homeless shelters, and specific stress factors such as reentering school and the work world also are underway. Counseling programs designed specifically to improve the coping skills of Black and Hispanic women at risk of HIV infection, and to prevent HIV infection among pregnant women, are also being assessed.

In addition, a new services demonstration program was initiated to target substance abusing pregnant and post-partum women and their infants, with particular emphasis on low income individuals. As you know, increasing numbers of infants are addicted at birth, and many are born with long-term disabilities

due to their mother's drug use during pregnancy. These projects are designed to promote the involvement and coordinated participation of multiple organizations in the delivery of comprehensive services for substance using pregnant and postpartum women, especially low income women, and their infants.

The National Institute of Mental Health routinely requests proposals singling out women in its study samples. Finally, NIMH has published a monograph entitled Women's Mental Health: Agenda for Research to encourage such studies on specific concerns of women.

Question. How many of ADAMHA's research projects are focusing on women?

Answer. In addition to its research projects, ADAMHA, through the Office for Substance Abuse Prevention, also supports various services demonstration projects which focus on women. Of the total 130 high risk youth demonstrations grants awarded in FY 1987, over 40 include pregnant teens among their target populations; three grants are devoted to exclusively to pregnant teens. Total expenditures for these latter grants during their eligible years of operation will amount to over $809,000. OSAP also anticipates awarding between 20-25 grants in August 1989 in the demonstration grant program to develop model projects for the prevention, education, and treatment of alcohol and other drugs.

Question. How many of ADAMHA's principal investigators are women?

Answer. In fiscal year 1988, the most recent year for which complete data is available, twenty-two percent of ADAMHA's principal investigators on research projects were women. In addition, a number of women are key investigators on projects on which they are not principal investigators.

PAYMENT SYSTEM FOR MENTAL HEALTH CARE

Question. We have made a great effort in Congress to eliminate "warehousing" of the mentally ill, and provide treatment in the community. By and large, that effort has been successful: 75% of mental health services are provided in the community. At the same time, we have tried to move from inpatient to outpatient care, which has been shown to be medically effective as well as cost effective. Yet 70% of the resources we put toward mental health are still going to hospitals for inpatient care. Why aren't the dollars following the patients where they are actually receiving treatment?

Answer. There are several reasons why it has been difficult to shift patient care funds from hospitals to community resources.

First, virtually all private health insurance policies and some major federal programs contain limitations on coverage for outpatient mental health care. Those limitations provide incentives to the use of inpatient care or, at least, tend to discourage the use of necessary outpatient treatment. Medicare,

for example, until recently provided only $250 a year for outpatient psychiatric benefits. Even now such benefits are limited to $1,100 a year. This special treatment for outpatient care, as contrasted to inpatient care, does not occur for other medical and surgical conditions.

Second, even though the census of state hospitals has declined significantly in the last fifteen years it has not been possible in most states to achieve a comparable reduction in the costs of these hospitals. This principally is due to the difficulty in reducing overhead costs in areas such as building maintenance, heat and other utilities, support personnel, etc..

FUNDING FOR SCHIZOPHRENIA AND FOR DEPRESSION

Question. According to the National Institute of Mental Health, there are about 1.6 million schizophrenics in America today, but there are between 10 and 15 million Americans suffering from depression. One in 14 of them will commit suicide successfully--others will try and fail. Some 40% of the spouses of Alzheimer's victims are suffering from serious treatable clinical depression, and NIMH estimates that 19% of the successful suicides in this country each year are from individuals over 65 years of age.

NIMH also says we are at a point where clinicians can treat and manage 80 to 90% of depressed patients. Please comment on NIMH's priority funding for activities related to schizophrenia versus depression, and insert a chart indicating funding for these activities.

Answer. The National Institute of Mental Health (NIMH) supports research on a broad spectrum of serious mental illnesses including both schizophrenia and depression. In the 1985 reorganization of NIMH, clinical research in each of these areas was consolidated into branches, which include the full range of research from etiology to pharmacology to psychosocial factors and treatments.

Historically, and continuing to the present, the program in depression, which includes mood and the closely related anxiety disorders, has been the largest of the clinical research branches. The schizophrenia program, despite the severity, chronicity and extent of suffering caused by this illness, was considerably smaller. In 1986, the NIMH began the development of a National Plan for Schizophrenia Research. The plan and its implementation have greatly strengthened the NIMH program of research in this illness.

At the same time, in the field of depression, the NIMH took a major step to disseminate the findings from research into the public's awareness. The NIMH launched a public education program entitled Depression Awareness, Recognition and Treatment (D/ART) program in May, 1988 to reduce the needless suffering of millions of Americans currently afflicted by an illness that can, for many, be successfully treated.

The NIMH remains deeply committed to supporting high quality research in both schizophrenia and depression. Both are fundamental to our mandate of reducing the suffering caused by mental illness.

What follows is a chart comparing funding for research in schizophrenia and for depression. The totals include funds for Extramural Research, Intramural Research, and Research Training.

Funding for Schizophrenia and Depression Research
(Amounts in thousands of dollars)

	1988 Actual	1989 Estimate	1990 Request
Schizophrenia	54,986	65,346	68,291
Depression	62,160	72,340	75,499
Total	117,246	137,686	143,790

ACCOMPLISHMENTS OF THE
DEPRESSION AWARENESS RECOGNITION AND TREATMENT (D/ART) PROGRAM

Question. What progress can you report on NIMH's Depression Awareness, Recognition, and Treatment (D/ART) campaign?

Answer. D/ART is a public and professional education program designed to increase knowledge and awareness, change attitudes and beliefs, motivate changes in behavior about depression, and improve treatment. It is a multi-faceted and balanced approach, including the following strategies:

- Continuing Education Training Programs for health and mental health providers in the diagnosis and treatment of depressive disorders were initiated in 1986 and are now providing more than two training programs each week somewhere in the United States. These programs are being provided through health and mental health associations, through NIMH-sponsored workshops at professional meetings, and through six Clinical Training grants to Universities and Medical Schools. Another training grant has completed its activities, and several new proposals are in review.

- The Public Education Campaign launched in May 1988 uses TV and radio spots, fact sheets, brochures, and pamphlets in English and Spanish to educate the public about the symptoms of depressive disorders and the availability of treatment. For example, the first television public service announcement received air time estimated at close to one million dollars and, according to the Broadcast Advertisers Reports, reached a third of all American homes. NIMH has received more than 100,000 requests for

information about depression from depressed people, family members, and other interested citizens.

- Community Partnerships have been organized in 29 sites in 21 States to educate the public and professionals about depression. They provide professional education, public information, materials development, mutual support groups, and referrals for treatment within their communities. During the first year of the Public Education Campaign, the Community Partners received local contributions of more than three times their Federal support as well as 18,500 hours of local staff and volunteer time.

- A Worksite Program has been initiated among Fortune 500 corporations to conduct education in the worksite and to encourage insurance coverage for treatment of depression in benefits plans. Led by the Washington Business Group on Health, these corporations have joined with NIMH to plan a cost containment program designed to increase the availability of coverage for treatment, while reducing the time lost from work due to depression.

- As a major private/public enterprise to benefit the mental health of the American public, D/ART continues to collaborate with the private sector. D/ART actively involves intermediary organizations such as each of the major health and mental health professional associations, major mental health advocacy groups, and major health groups concerned with needs of special populations in addition to businesses, unions, insurance and pharmaceutical industries, and the media. For example, a pharmaceutical company has reprinted and nationally distributed 2 million copies of a D/ART brochure plus 200,000 Spanish copies and 100,000 posters.

DOMESTIC VIOLENCE PROGRAMS

Question. Studies show that children who grow up in homes where there is abuse--violence, or drug or alcohol abuse--have a lot of trouble breaking out of the same pattern. What work is ADAMHA doing on this issue? Please describe the research and the services effort.

Answer. This issue is receiving a lot of attention in ADAMHA. A description of key activities follows.

In NIMH, a recently completed study found a positive association between spousal discord and aggression and hyperactivity in the children. Children from the ages of six to thirteen were studied in four types of families: those where the wife and children spent time at shelters for victims of domestic violence; those where violent couples lived exclusively at home; those where couples were nonviolent but contentious; and those where couples were congenial. In an NIMH telephone survey of over 3,000 parents and children living at home, NIMH found that the risk of certain problems among children (for example: fights, poor

grades, and drug abuse) was almost twice as high in families where violence existed. A five-year NIMH study to begin this fall will examine the multiple effects of marital violence and conflict on preschool and preadolescent children.

NIAAA examines environmental and genetic factors in order to assess the transmission from one generation to the next of susceptibility to alcohol problems. Evidence now suggests that at least some forms of alcoholism are inherited and scientists are searching for specific genes involved in that phenomenon. The role of non-inherited familial factors also is being studied over a protracted period of time; developmental characteristics of children and their reactions on various psychological tests are being examined in order to identify children at high risk for whom preventive interventions may be successfully applied. NIAAA research also is focussed on the relationship between alcohol abuse and violence. One study that is focussing on alcohol-related violence and its connection with panic, depression and certain personality disorders may help develop biological means of identifying and treating high-risk individuals.

NIDA is studying the relationship between drug abuse and domestic violence. In addition, data from NIDA's National Household Survey on Drug Abuse shows that children are more likely to abuse drugs if an older sibling or parent has abused them. In addition, a longitudinal study shows that abuse by the sibling or parent significantly affects the child's attitude toward drugs and is correlated with emotional problems. In a follow up study, NIDA is investigating the epidemiology of drug use in adulthood across generations.

OSAP's high risk youth demonstration program focuses on the many biological, behavioral and environmental factors affecting substance abuse among high risk youth, including domestic violence.

OSAP also has established a working group of its grantees to develop prevention strategies that might be most effective in helping children of substance abusers to deal with child abuse and other domestic violence and to reduce the risk of their becoming substance abusers themselves.

DOMESTIC VIOLENCE AND SUBSTANCE ABUSE

Question. What kind of overlap is there between alcohol abuse and/or drug abuse and domestic violence against spouses on children?

Answer. There is clearly a relationship between alcohol and drug abuse and domestic violence. However, precise data on that relationship is not available. Recent research findings indicate that distinct subgroups of alcoholics may be particularly prone to domestic violence, and that these subgroups may exhibit certain genetically determined biochemical traits that may be predictive of continuing violent behavior.

A 1985 scientific survey found that the likelihood of a severe assault against a wife increases threefold among high moderate- to high-level drinkers and increases by a factor of seven among binge

drinkers. On the other hand, the same survey found that most males who are heavy drinkers do not assault their wives, and many assaults take place when both spouses are sober. The relationship between domestic violence and other drug abuse is less clear. One study implicates cocaine in domestic violence and research suggests that amphetamines may be implicated in such problems as well. There is some evidence that marijuana, opiates and LSD are not likely to contribute to the occurrence of violence.

ABUSE OF THE ELDERLY

Question. What work has been done or is underway on the issue of elder abuse?

Answer. NIMH, through research and research training grant support to the Family Violence Research Project at the University of New Hampshire, has contributed to the emerging literature on elder abuse and to development of a notable study of the prevalence of elder abuse which was conducted with grant support from the National Institute on Aging. This study, under the direction of Karl Pillemer, Ph.D., and David Finkelhor, Ph.D., obtained a random sample of all elderly persons (65 or older) residing in the community in the Boston metropolitan area. Some 2,000 elderly persons were interviewed for physical abuse (e.g., being pushed, grabbed, shoved, assaulted with a weapon), neglect (the serious or frequent deprivation of assistance needed for activities of daily living), and psychological abuse (frequent insults or threats in the preceding year).

The data indicated that physical violence was the most frequent form of abuse (occurring at a rate of 20 per 1,000), with psychological abuse (chronic verbal aggression) the second most frequent abuse (11 per 1,000). Neglect showed the lowest rate (4 per 1,000). Of those who were physically abused, 63% had been pushed, grabbed or shoved, 45% had something thrown at them, 42% had been slapped, and 10% had been hit with a fist, bitten, or kicked.

While 58% of the abusers were spouses, as compared to 24% who were children of the elderly, this reflected the extent to which the elderly victim resided with a spouse rather than with a child. The rate of abuse for those living with a spouse (41 per 1,000) was actually slightly less than the rate for those who were living with their children (44 per 1,000). And because they were far more likely than elderly women to live with a spouse, the risk of elderly men being abused was more than twice that for elderly women (53 versus 23 per 1,000). However, elderly women were far more likely than men to suffer injuries as a result of abuse.

FREQUENCY OF SPOUSE ABUSE

Question. In 1985, nearly 1.6 million wives were battered and abused by their husbands. We're all familiar with the case of Joel Steinberg, who beat his adopted daughter to death, and broke the spirit and the bones of his partner, Hedda Nussbaum. This tragic case raises so many questions about the nature of abuse, treatment,

and especially prevention. Women's rights advocates say this kind of extreme violence is not unusual. Is this true?

Answer. Unfortunately, spouse abuse is all too common. Based on a 1985 NIMH national survey, investigators estimate that some 1,600,000 wives were severely assaulted during that year. In addition to the physical and psychological trauma of such abuse, battered women are also placed at increased risk of psychiatric problems, such as depression and agoraphobia--an abnormal fear of being outside the home.

EFFORTS TO REDUCE ABUSE

Question. What resources is NIMH focusing on the issue of spouse abuse?

Answer. For a decade and a half NIMH has supported significant research on domestic violence. This research has included:

1) a 1975 national phone survey which provided the first major scientific data on the prevalence and nature of domestic violence and a 1985 resurvey;

2) a study on the identification of battered women in hospital emergency rooms which called attention to the ability to identify these cases; and

3) a study on the etiology of marital violence which pointed out the extent to which pre-marital aggression continued after marriage and the notable role of communication problems as a predictor of physical aggression.

In FY 1989, NIMH will expend $900,000 for five grants to support a clinical investigator award and a minimum of four research grants whose primary emphasis is marital aggression and violence. These grants are:

1) Daniel Saunders, Ph.D., "The Traumatic Aftermath of Violence Against Wives." Under this three-year grant, which will begin its final year in FY 1989, Dr. Saunders is pursuing advanced research training and research on the psychological trauma experienced by battered women.

2) William Davidson, Ph.D., "Effects of Alternative Interventions for Battered Women." This three-year project, which began on February 1, is evaluating the effects of an advocacy intervention on the psychological health and subsequent abuse of battered women.

3) Frank Dunford, Ph.D., "Extension of the Omaha Spousal Abuse Experiment." This one-year grant, which has a May 1 start date, involves an extension from six months to three years in the evaluation of the duration of effects of various police responses to domestic violence calls (e.g., advise, separation, arrest, or warrant).

4) Neil Jacobson, Ph.D., "Marital Violence: Cognitive and Physiological Correlates." This four-year grant, which had a April 1 start date, seeks to identify more precisely the antecedents, consequences, and concomitants of marital violence, with a particular focus on the role of marital communication, cognitive processing of relationship events, and autonomic nervous system arousal.

5) Gayla Margolin, Ph.D., "Marital Conflict: Intrapersonal & Interpersonal Factors." This five-year project, for which funding will begin September 1, is focusing on the effects of marital conflict and violence on preschool and preadolescent children. The study will also examine the mediating effects of the parent-child relationship and personal characteristics of the children on the effects of marital discord and violence.

Question. Can we take heart from the studies--how can we work to reduce domestic violence?

Answer. Research studies are helping to answer fundamental questions about the extent and nature of domestic violence. For example, NIMH funded research has indicated that later spouse abuse is often evident during courtship and that male batterers are often involved in a series of battering relationships. Moreover, research is becoming more sophisticated in this area as evidenced by improved methodology and sampling in large national surveys of family violence funded by NIMH in 1975 and 1985. Such studies have helped to promote an increasing awareness among professionals and the general public about the extent, seriousness, and nature of domestic violence and have provided a much firmer knowledge base on which to plan interventions and prevention programs.

EFFECTIVENESS OF IV DRUG ABUSE PREVENTION PROGRAMS

Question. How effective have programs aimed at IV and other drug abusers been in preventing the spread of infection?

Answer. In 1987, NIDA developed and implemented a nationwide AIDS demonstration research prevention program targeted to intravenous drug users who are not in treatment, and to their sexual partners. At this time NIDA has funded 41 projects establishing 63 demonstration research sites. Virtually all projects are funded for a three year period and all are now in the process of gathering data and evaluating the efficacy of the different preventive interventions initiated.

All projects make use of certain core elements to guarantee the collection of data in a standardized format that will allow the rigorous evaluation of preventive strategies.

(a) A standardized structured interview schedule is administered to all intravenous drug users and sexual partners receiving preventive interventions. The interview schedule explores risk-taking behaviors

associated with drug use and with sexual behaviors. HIV testing is made available.

(b) The vast majority of grant-funded projects--and all those funded within the past 18 months--make use of a clinical trials paradigm. As a part of NIDA's research, special effort is made to gather sufficiently large samples of blacks, Hispanics and whites, and of females and males, to guarantee an understanding of the efficacy of different interventions with those populations.

(c) Each project is developing a detailed protocol describing the nature and functioning of the preventive interventions in use. Thus, those interventions found effective can be made available to other comparable communities for their use.

(d) All projects are making use, or will make use, of a standardized structured interview schedule administered to all individuals at six months followup after implementation of the interventions. Again, the interview schedule assesses risk-taking behaviors to learn whether or not there has been any diminution in risk-taking behaviors in the groups exposed to preventive interventions, and whether the groups exposed to innovative preventive interventions show greater diminution in risk-taking than those exposed to standard interventions. In addition, because all individuals are offered HIV testing at intake and followup, rates of seropositivity can also be studied and compared between groups.

One example of a successful intervention is in San Francisco. A study conducted between 1986 and 1988 has demonstrated that street-based education of IVDAs continues to show important improvement in injection-associated HIV transmission risk. Furthermore, the changes in needle hygiene appear to have lowered the overall risk of HIV infection among IVDAs in San Francisco, and appears to be a factor in attenuating the spread of HIV.

COORDINATION WITH CDC

Question. How does NIDA coordinate counseling and testing of IV drug abusers with CDC's activities of the same nature?

Answer. CDC has funded HIV testing and counseling in drug abuse treatment programs in 20 States. That testing is available to NIDA's outreach demonstration research grants and contracts as well as NIDA's HIV seroprevalence monitoring program. With specific regard to the outreach demonstration research program, NIDA and CDC schedule joint site visits and hold cooperative regional conferences to assure cooperation and a sharing of information. In addition, NIDA provides training opportunities to staff of State health departments, again acting in conjunction with CDC, to provide support for education in activities relating to intravenous drug users and their sexual partners. NIDA plans a further expansion of its training program in conjunction with CDC to develop still closer coordination between State drug abuse

agencies and State health departments and to increase numbers of health service workers in training.

In association with NIDA's seroprevalence study, CDC has transferred funds to NIDA to support comprehensive testing and counseling without duplication of effort or services. CDC and NIDA staff routinely discuss testing and counseling services in communities participating in the seroprevalence study, and NIDA submits quarterly reports to CDC regarding services provided.

To further assure cooperation, NIDA and CDC meet regularly as a part of scheduled monthly meetings of the PHS Addiction and Behavior Subgroup.

EFFECTIVENESS OF NEEDLE EXCHANGE AND OTHER PREVENTION PROGRAMS

Question. How does the current availability of services for drug treatment affect HIV prevention efforts? Are interim measures, including needle exchange, bleach, and "no frills" methadone programs, effective in preventing the spread of the HIV infection?

Answer: The most effective strategy for changing risk-taking behaviors related to intravenous drug use is through involvement in long-term drug abuse treatment. Studies have established a relationship between length of time in treatment and change in drug using behavior. Thus a key element in AIDS prevention programs working with intravenous drug users out of treatment is to get those users into treatment. However, the lack of treatment slots in some communities is a problem.

Because of the concern that a needle exchange program could be viewed as sanctioning IV drug abuse, the Administration is strongly opposed to such programs. We await better solutions to the twin scourges of AIDS and IV drug abuse. We cannot yet speak to the efficacy of this and other interim measures available to contain the spread of HIV infection. There is some evidence, however, that, in those communities in which bleach is made available, there is a marked increase in its use to halt infection.

NIDA and the FDA recently proposed revised conditions for the use of methadone in maintenance treatment programs to permit programs to provide interim treatment to those awaiting placement in comprehensive treatment and to require programs to provide counseling on avoidance of HIV transmission. These requirements are being proposed in response to the HIV epidemic and are intended to allow more narcotic addicts into treatment more quickly, thereby decreasing the incidence of intravenous drug abuse and the transmission of HIV. A recent study showed that a similar approach is successful in reducing needle sharing.

We recognize that shortages of funds, facilities, and trained personnel limit the immediate expansion of narcotic treatment programs. We are also aware of waiting lists for methadone and other treatment in many localities. The changes proposed by FDA and NIDA, as well as Waiting List Reduction Grants being awarded by

this agency, will permit programs to provide additional treatment in order to help alleviate the human suffering of addicted individuals and to reduce the abuse of IV drugs.

INCREASED FUNDING FOR THE HOMELESS MENTALLY ILL

Question. As part of the President's commitment to fully fund the McKinney Homeless Assistance Act, you have proposed to increase the budget for mental health services for the homeless by $56 million. What plans or special initiatives do you have if you receive this substantial increase over the initial budget request submitted by President Reagan?

Answer. President Bush's 1990 budget includes a request for $11.5 million for Section 612 of the Stewart B. McKinney Homeless Assistance Act (Community Mental Health Services Demonstration Projects for Homeless Person Who Are Chronically Mentally Ill). If these funds are appropriated, the National Institute of Mental Health plans to support the following projects:

1) approximately 20 new research demonstration awards in which promising service programs for homeless severely mentally ill adults and homeless families with children at risk of emotional disturbance can be rigorously tested;

2) continuation of approximately 10 research demonstration grants initially funded in fiscal year 1989;

3) continuation of a national evaluation of the comprehensive service system projects initially funded in fiscal year 1987 under the McKinney Act; and

4) support of the third year of the National Resource Center for Homelessness and Mental Illness (a technical assistance center and national clearinghouse).

President Bush's 1990 budget also requests $35 million for Section 611 of the Stewart B. McKinney Homeless Assistance Act (Block Grant Program for Service to Homeless Individuals who are Chronically Mentally Ill) The purpose of these grants is to provide an infusion of funds to all of the States, the District of Columbia, and the Territories for five services: outreach, case management, mental health treatment, and supportive housing for homeless mentally ill persons, as well as training for service providers. The proposed amount is an increase of more than $20 million over that which was submitted by President Reagan. This increase in funding would allow States, especially the larger ones, to begin to rebuild service programs for the homeless mentally ill which had been previously reduced.

Finally, the Bush Budget also includes $17 million for McKinney grants to be awarded by the National Institute on Alcohol Abuse and Alcoholism. That money will fund about 18 research demonstration projects as well as two contracts for cross-site, national evaluation. The goal of this program is to develop and test innovative treatment models targeted to this population. For each project, researchers and service providers will collaborate.

Five service models at multiple sites and including outreach, intensive case management, residential-based services, and systems level interventions will be evaluated.

NIAAA will collaborate with both NIDA and NIMH in developing the treatment models to be tested. Evaluation of the treatment effectiveness on individual patients will receive the highest priority. Sites will be required to collect data on a prescribed set of treatment outcome measures and must also use common research designs. Emphasis will be placed on describing the implementation of the treatment models in order to facilitate replication of those that are effective. A cross-site analysis of treatment outcome also will be conducted.

SERVICE DELIVERY PROGRAMS FOR THE HOMELESS MENTALLY ILL

Question. A significant portion of the homeless are chronically mentally ill and are substance abusers. How are you adapting service delivery to reach these people?

Answer. ADAMHA-supported research on the homeless mentally ill population suggests that dual diagnoses of mental illness and substance abuse are common. Nearly half of the population has been estimated to be abusing alcohol and/or drugs. In an NIMH study conducted in Los Angeles, for example, 46% of those who were seriously mentally ill were found to be chronic substance abusers. Since use of any alcohol or drugs at all among severely mentally ill persons is often considered to be abuse, these figures may even underestimate this widespread problem.

ADAMHA has mounted several efforts to stimulate research, to develop further knowledge on the special service needs of homeless mentally ill individuals who are substance abusers, and to disseminate this information to policy makers and service providers. A summary of these efforts follows.

A recent NIMH research announcement, "Research and Research Demonstrations on Homeless Severely Mentally Ill Adults And Homeless Families With Children Who Are At Risk Of Severe Emotional Disturbance" encourages epidemiological and service systems research on the dually diagnosed among the homeless.

Two other recent NIMH research announcements, "Epidemiological Studies of Persons with Mental Disorders that Co-Occur with Alcohol and/or Drug Abuse Disorders" and "Research on Services for Person with Mental Disorders that Co-Occur with Alcohol and/or Drug Abuse Disorders" include the homeless as a subpopulation for study.

The McKinney Mental Health Services Demonstration in Oregon (funded by NIMH under Section 612 of the Act) focuses on serving homeless mentally ill persons who are substance abusers. This program provides mental health and substance abuse treatment including screening and diagnosis, treatment planning, evaluation of treatment, prescription and medication management, drug and alcohol abuse detoxification and treatment, and psychosocial rehabilitation. All of the other NIMH-funded McKinney

demonstration projects include dually diagnosed individuals in their target populations for receipt of services.

Of the nine currently active homeless research demonstrations supported by NIAAA, two are targeted to homeless individuals who suffer from mental illness as well as alcohol or other drug abuse. One of these, located in Philadelphia, is testing a rehabilitation program that provides three levels of residential setting: a therapeutic community in a structured environment; personal care boarding homes; and supportive living programs. The other program is located in Anchorage and provides a reception center with diagnostic screening and a drop-in detoxification area. Combining many community resources, the program provides shelter for those homeless turned away from other facilities because they are inebriated or mentally ill. The program also provides needed medical, diagnostic, and mental health and alcohol treatment opportunities and includes a strong vocational education component.

Various knowledge development projects have been undertaken by NIMH to focus on homeless mentally ill persons who are substance abusers (e.g. annotated bibliographies, literature reviews, monographs on treatment and training, etc.) and to disseminate these materials to providers and policy makers.

PROGRAMS FOR THE HOMELESS MENTALLY ILL IN RURAL AREAS

Question. What is the current level of support for programs that serve homeless in rural areas who are mentally ill or substance abusers?

Answer. The Mental Health Services for the Homeless Block Grant, funded under Section 611 of the McKinney Act, allocates funds on a formula basis to all states--including predominantly rural States--and the territories for services for the homeless mentally ill population. As is the case with other block grants, States have discretion over the distribution and use of funds within the State and national reporting requirements are minimal. Therefore, ADAMHA has no specific data on use of these funds in rural areas.

However, a review of block grant applications suggests that some States planned to distribute funds statewide, either evenly to different service areas or using a formula.

The recent NIMH research announcement on homelessness and mental illness encourages studies of specific subpopulations, including persons living in rural areas. Thus, some of the applications received and funded under this announcement may improve our understanding of the problem of rural homelessness among the mentally ill.

INTRADEPARTMENTAL SERVICE AGREEMENTS

Question. Please provide the Subcommittee with a list of the service agreements between ADAMHA and other PHS agencies.

Answer. A complete list of current agreements follows. Since most such service agreements are renewed near the end of the fiscal year, most of those listed obligate fiscal year 1988 funds; a few obligate fiscal year 1989 funds.

Fiscal Year 1988

NIMH Funds IN

1. National Institutes of Health (National Institute of Neurological and Communicative Disorders and Stroke) $282,600--Partial support of Grant MH 31862 "Brain Tissue Resource for Neurological and Psychiatric Diseases."

2. Health Resources and Services Administration $30,000--Support of a joint NIMH-OMCH invitational workshop on financing of mental health services for children and adolescents.

3. National Institutes of Health (National Center for Nursing Research) $59,630--Partial support of Grant 1 RO1 MH43747-01 "HIV Antibody Testing: Developing Guidelines for Screening Perpetrators and Victims of Sexual Abuse."

4. National Institutes of Health $76,000--To support activities of the DHHS Advisory Panel on Alzheimer's Disease (FY 88 & FY 89), including workgroup meetings, preparation and issuance of annual reports to Congress.

5. Office of the Assistant Secretary for Health (National Center for Health Services Research and Health Care Technology Assessment) $5,000--To support activities of the DHHS Advisory Panel on Alzheimer's Disease (FY 88 & FY 89), including workgroup meetings, preparation and issuance of annual reports to Congress.

6. Office of the Assistant Secretary for Health (Office of Health Planning and Evaluation) $100,000--To perform an evaluation of a nine-city, five year demonstration of health care for the chronically mentally ill.

NIMH Funds OUT

1. Health Resources and Services Administration (Bureau of Health Care Delivery and Assistance) $5,000--To reimburse BHCDA for one Commissioned Officer for Student Training and Extern program.

2. Food and Drug Administration $50,000--To coordinate with FDA in their contract with the "Forum" (IOM).

3. National Institutes of Health (Division of Research Resources) $1,250,000--To provide funds to support minority biomedical research support programs which includes direct and indirect costs.

4. Centers for Disease Control (National Center for Health Statistics) $43,050--To monitor the contractor's work on the Continued Followup of Total Cohort 1987 and prepare analytic data tapes (NHANES I Epidemiologic Followup Study).

5. Health Resources and Services Administration $500,000--To help support a conference regarding the implementation of P.L. 99-457, the Education of the Handicapped Act Amendment s of 1986. A paper will be developed arter the meeting articulating an overall philosophy and set of principles for mental health participation in the development of a comprehensive service system for handicapped and "at risk" children, age birth through five.

6. National Institutes of Health $20,856,000--NIMH Management Fund--NIH to provide research and administrative support services to the NIMH.

7. Office of the Assistant Secretary for Health (National Center for Health Services Research and Health Care Technology Assessment) $35,165--To support AHRS annual conference and to disseminate information through the Focus newsletter.

8. Centers for Disease Control (National Center for Health Statistics) $88,974--NHANES III--Statistical survey to continue through 1994 ($119,242 for FY 1989). Total cost of $1,036,296.

9. Centers for Disease Control (National Center for Health Statistics) $33,000--The NCHS will conduct a survey "A National Maternal and Infant Health Survey" for NIMH.

10. Office of the Assistant Secretary for Health (Office of Disease Prevention and Health Promotion) $50,000--To transfer funds in support of an ODPHP cooperative agreement with the Washington Business Group on Health to support and implement a National Worksite Program for NIMH's Depression/Awareness, Recognition and Treatment Program.

11. National Institutes of Health (National Institute of Child Health and Human Development) $200,000--To support a contract designed to obtain information on "Social and Behavioral Aspects of Health and Fertility Related Behaviors."

12. National Institutes of Health (National Institute of Neurological and Communicative Disorders and Stroke) $4,000--To support a grant for a "Symposia Support for Arachidonic Acid Conference."

13. Indian Health Service $15,000--To establish a formal mechanism for the regular exchange of information in areas of common interest and shared responsibility. (Institutes/OSAP to share equally--$15,000 each.)

14. Public Health Service $111,000--To provide PHS and the Office of the Secretary with services related to television and radio production on Aids and Youth Homicide Prevention. (Three Institutes share in funding: NIMH, $111,000; NIDA, $73,000; NIAAA, $16,000.)

15. National Institutes of Health (National Institute of Child Health and Human Development) $25,000--In support of a conference

(grant) of International Congress of Psychology in Australia, August 28-September 3, 1988.

16. Health Resources and Services Administration (Bureau of Health Care Delivery and Assistance) $10,000--To support a jointly sponsored conference for the primary health care projects administered by BHCDA dealing with homeless mentally ill persons.

17. National Institutes of Health $215,000--NIMH to reimburse NIH for accounting services for the intramural program.

NIDA Funds IN

1. Centers for Disease Control $1,000,000--CDC shall transfer these funds to NIDA in FY 88. FY, 89 and FY 90 to support HIV testing and counseling services within selected drug abuse treatment programs.

2. Food and Drug Administration $14,046--To transfer funds to NIDA so that selected NIDA scientists will be able to perform drug reviews on New Drug Applications and Notices of Claimed Investigational Exemption for a new Drug.

3. Food and Drug Administration $5,000--To share costs with FDA, DEA, and NIDA for a meeting to review current methods for the prediction and evaluation of drug abuse liability testing in humans.

4. Food and Drug Administration $105,700--The NIDA/Addiction Research Center shall study the effects of chronic administration of drugs on the density of serotonin, dopamine and norepinephrine uptake sites in rat brain.

NIDA Funds OUT

1. Food and Drug Administration $747,531--NIDA will reimburse FDA for studies on the effects of marijuana smoke on the brain, behavior or other neuropathological alterations.

2. Indian Health Service $15,000--To establish a formal mechanism for the regular exchange of information in areas of common interest and shared responsibility (Institutes/OSAP share equally-- $15,000 each.)

3. Centers for Disease Control $50,000--To provide technical assistance in conducting the proposed establishment of a national agenda for behavioral research to control the AIDS epidemic.

4. Public Health Service $73,000--To provide PHS and the Office of the Secretary with services related to television and radio production on Aids and Youth Homicide Prevention. (Three Institutes share in funding: NIMH, $111,000; NIDA, $73,000, NIAAA, $16,000.)

5. Centers for Disease Control (National Center for Health Statistics) $270,000--To support the 1988 National Maternal and Infant Health Survey.

6. Food and Drug Administration $75,000--To support a study of the feasibility of collecting drug abuse data, identical to that gathered by the National Household Survey, by telephone interviewers, in years when the National survey is not conducted.

NIAAA Funds IN

1. National Institutes of Health (National Institute of Dental Research) $30,369--NIAAA to pay for animal caretaking services.

NIAAA Funds OUT

1. Indian Health Service $15,000--To establish a formal mechanism for the regular exchange of information in areas of common interest and shared responsibility (Institutes/OSAP share equally--$15,000 each.)

2. Centers for Disease Control (National Center for Health Statistics) $53,550--To support the followup for National Health and Nutrition Examination Survey.

3. Centers for Disease Control (National Center for Health Statistics) $200,000--To partially support the 1988 National Maternal and Infant Health Survey.

4. National Institutes of Health $3,186.000--NIH to provide research and administrative support services for the NIAAA Clinical Research Program.

5. Centers for Disease Control (National Center for Health Statistics) $568,725--To support the 1988 National Health Interview Survey (NHIS) Alcohol Consumption Supplement.

6. National Institutes of Health (Division of Research Resources) $307,298--For support of the Minority Biomedical Research Support Program.

7. Health Resources and Services Administration (Bureau of Health Care Delivery and Assistance) $5,000--To support and sponsor a conference for the primary health care projects administered by BHCDA.

8. Centers for Disease Control $66,000--To support services performed by CDC such as conduct surveillance of selected alcohol-related injuries in three communities; conduct problem-specific interventions directed at reducing alcohol-related injuries in at least one of the communities, and utilizing the surveillance systems established in the communities, evaluate the outcome effects of the intervention(s).

9. Public Health Service $16,000--To provide PHS and the Office of the Secretary with services related to television and radio production on Aids and Youth Homicide Prevention (Three Institutes share in funding: NIMH, $111,000; NIDA, $73,000; NIAAA, $16,000.)

10. National Institutes of Health (Division of Research Services) $59,005--Animal Care.

NIAAA Buildings and Facilities Funds OUT

1. National Institutes of Health (Division of Engineering Services) $100,000-- To review architectural plans.

OSAP Funds IN

1. Public Health Service (Office of the Assistant Secretary for Health) $50,000--In partial support of the Secretary's Second National Conference on Alcohol Abuse and Alcoholism.

2. Public Health Service (Office of the Assistant Secretary for Health) $165,000--To cover travel, per diem, registration and other costs associated with securing speakers for the Second National Conference on Alcohol Abuse and Alcoholism.

OASP Funds OUT

1. Food and Drug Administration $5,520--To provide joint sponsorship and dissemination of the Secretary's Housecalls messages on the topic of pregnancy.

2. Indian Health Service $15,000--To establish a formal mechanism for the regular exchange of information in areas of common interest and shared responsibility. (Institutes/OSAP share equally--$15,000.)

3. Centers for Disease Control $10,000--To help support the XIII World Conference on Health Education for sessions and/or workshops, translations, bursaries, proceedings, and exhibits.

4. Health Resources and Services Administration (Bureau of Health Care Delivery and Assistance) $300,000--Provide funding to conduct training of substance abuse counselors and other health professionals and assess the impact of the training initiative.

Fiscal Year 1989

NIMH Funds IN

1. National Institutes of Health $76,000--To support activities of the DHHS Advisory Panel on Alzheimer's Disease including workgroup meetings, preparation and issuance of annual reports to Congress.

2. National Center for Health Services Research and Health Care Technology Assessment $5,000--To support activities of the DHHS Advisory Panel on Alzheimer's Disease including workgroup meetings, preparation and issuance of annual reports to Congress.

NIMH Funds OUT

1. National Institutes of Health (Division of Research Services) $16,558--To reimburse NIH for space and basic animal care for behavioral studies involving primates.

2. National Institutes of Health $183,900--NIMH to reimburse NIH for accounting services for the Intramural Program.

3. National Institutes of Health (Division of Research Services) $17,279--Prorata share for the costs of the overall Primate Unit program.

4. National Institutes of Health (National Institute of Child Health and Human Development) $439,861--Collaboration on brain/behavior research at the NIH Animal Center, Poolesville, Maryland.

5. National Institutes of Health $23,835,000--NIMH Management Fund. The NIMH to reimburse NIH for research and administrative support services.

6. National Institutes of Health (Division of Research Services) $75,000--NIMH to reimburse the Service and Supply Fund (NIH) for the Management Fund Assessment charge for utilities and facility maintenance related to the shared animal facility.

7. Centers for Disease Control (National Center for Health Statistics) $33,000--To support the National Maternal and Infant Health Survey.

8. Centers for Disease Control (National Center for Health Statistics) $119,242--NHANES III statistical study (The Epidemiology of Depression and Mania.

9. Centers for Disease Control (National Center for Health Statistics) $47,000--National Death Index (NDI) file searches of NIMH study subjects to determine if any subjects may have died.

10. Office of the Assistant Secretary for Health (Disease Prevention and Health Promotion) $100,000--To support a National Worksite Program for Depression/Awareness, Recognition and Treatment.

11. Centers for Disease Control (National Institute of Child Health and Human Development $13,000--Keypunching information on children from the NINCDS Collaborative Perinatal Project to provide information for matching with the National Death Index.

12. Office of the Assistant Secretary for Health (National Center for Health Services Research and Health Care Technology Assessment) $30,000--To support two special mental health services research workshops at the 1989 annual meeting of the Association for Health Services Research and to disseminate FOCUS newsletter.

NIDA Funds OUT

1. Health Resources and Services Administration (Bureau of Health Care Delivery and Assistance) $9,015,000--To support demonstration grants to community-based health care organizations to expand drug abuse treatment capacity.

2. Food and Drug Administration $693,474--To study the effects of marijuana smoke on the brain, behavior, or other neuropathological alterations.

NIAAA Funds OUT

1. Office of the Assistant Secretary for Health (Office of the Surgeon General) $35,000--To provide support for the Surgeon General's Workshop on Drunk Driving.

2. Food and Drug Administration $50,000--To cosponsor a Forum on Drug Development and Regulation.

3. Centers for Disease Control (National Center for Health Statistics) $117,600--To support the National Health Interview Survey (NHIS) Alcohol Consumption Supplement.

4. National Institutes of Health (Institute of Diabetes and Digestive and Kidney Diseases) $6,250--Partial support for a conference on Regulation of Liver Gene Expression.

5. National Institutes of Health (Division of Research Services) $59,005--To provide facilities and animal care services to support study on alcohol tolerance using rats.

6. National Institutes of Health $3,602,000--To provide research and administrative support services for the NIAAA Intramural Research program.

7. National Institutes of Health (Division of Research Resources) $328,200--To support the Minority Biomedical Research Support Program.

8. Centers for Disease Control (National Center for Health Statistics) $36,400--To support the 1990 Longitudinal Followup of mothers in the 1988 National Maternal and Infant Health Survey.

NIAAA BUILDINGS & FACILITIES Funds OUT

1. National Institutes of Health (Division of Engineering Services) $30,000--To upgrade the floors for the new NIAAA animal facility.

OSAP Funds OUT

1. Office of the Assistant Secretary for Health (Office of Disease Prevention and Health Promotion) $100,000--To augment the study

entitled: "Evaluation of Effective Communications Strategies for Health Information to High Risk Youth Outside of School."

2. Centers for Disease Control (Office on Smoking and Health) $100,000--To develop a film for use by schools in changing the student body's attitudes towards tobacco and alcohol use.

OA Funds OUT

1. National Institutes of Health $4,200--To provide financial support for the planning and conduct and co-sponsorship of the Commissioned Corps Centennial Science Symposium.

SERVICES VERSUS RESEARCH

Question. Is ADAMHA pursuing a policy of phasing out its service programs to focus on research exclusively?

Answer. No, ADAMHA is not phasing out its service programs. We are exploring within the Department whether these programs would be more appropriately located in an agency whose mission is more focused on the provision of services, since the primary mission of the ADAMHA institutes is to contribute scientific solutions to the treatment and prevention of mental and addictive disorders.

DATA COLLECTION ACTIVITIES

Question. What portion of the budget for drug research and treatment is used for data collection? Please provide the Subcommittee with a history of the funding used for data collection, and with a chart showing the funding allocated for evaluations of drug abuse treatment, prevention, and educational programs.

Answer. In fiscal year 1989 approximately 16 percent of NIDA's regular (non-AIDS) budget will be devoted to data collection activities. Dollar amounts for data collection for the last eight fiscal years follows.

Evaluations

(Amounts in thousands of dollars)

1982	1983	1984	1985	1986	1987	1988	1989
6,077	6,015	8,869	8,287	8,009	11,275	11,617	31,380

Treatment Evaluation

(Amounts in thousands of dollars)

1982	1983	1984	1985	1986	1987	1988	1989
4,434	5,894	5,301	6,026	6,721	13,412	14,957	65,322

Prevention & Education

(Amounts in thousands of dollars)

1982	1983	1984	1985	1986	1987	1988	1989
2,874	3,945	4,735	5,946	6,191	10,163	10,065	12,647

Total

(Amounts in thousands of dollars)

1982	1983	1984	1985	1986	1987	1988	1989
13,385	15,854	18,905	20,259	20,921	34,850	36,639	109,349

NATIONAL REPORTING PROGRAM

Question. The National Reporting Program is the only source of national data on mental health services in the country. How do you view the experience of strengthening the program, and how can it be made a more useful resource?

Answer. The National Reporting Program has been strengthened through FY 1989 Block Grant funds made available under the Anti Drug Abuse Act of 1988. These funds have been used to purchase the 1990 organizational inventory and the 1990 patient survey, as well as to purchase two projects that will strengthen the role of the State mental health agencies and national organizations in the national data collection process. The latter two projects will examine the feasibility of decentralizing organizational data collection to the State mental health agencies and of improving patient data collections through the use of State data systems. Both will be facilitated through the current implementation of the Mental Health Statistics Improvement Program, a collaborative State-NIMH project to develop core data elements with common definitions. It is anticipated that these two projects will be awarded to the National Association of State Mental Health Program Directors Research Institute, Inc..

Currently, the National Reporting Program is undergoing an important review by a group of expert peers from the field. This review is necessary to clarify the types of data that should be collected by the Program, the mechanisms by which this should be done, and the types of information dissemination that should be carried out. It is anticipated that this review will make a significant contribution to the Program. Likely next steps will include greater decentralization of data collection processes and more synthetic and analytical work by NIMH. Addressing these issues will greatly enhance the value of the National Reporting Program to the entire mental health field.

STABILIZATION OF THE PROGRAM

Question. How can the program be stabilized over time?

Answer. At the present time, the National Reporting Program is undergoing an important review by a group of expert peers from

the field. This review group is examining how the Program can be stabilized over time. Likely options for the future include the development of sample studies and increased reliance upon State mental health agencies for faster, easier data collection. This development is made possible because of the current implementation of the Mental Health Statistics Improvement Program, a collaborative State-NIMH project to develop core data elements with common definitions.

For future years, several options will be considered to supplement activities funded by contract funds. The new grant program to upgrade State data systems should allow us to collect some data more efficiently and economically in the future, directly through the State agencies. Another alternative is to support more targeted surveys, perhaps on a sample basis, and using special research grant announcements rather than contracts. We hope that such alternatives will be elaborated by our panel that is assessing the National Reporting Program. Their report is expected by the end of this year.

WOMEN AND MINORITIES ON ADAMHA ADVISORY BOARDS

Question. What is the percentage of women and minorities on ADAMHA's advisory boards? Please provide a breakdown of the members by profession.

Answer. ADAMHA advisory committees are composed of 9 percent minority representation and 23 percent female representation.

ADAMHA's initial review groups, Boards of Scientific Counselors, and Extramural Science Advisory Boards are composed of virtually all active researchers from universities, hospitals, and research institutions.

Three quarters of ADAMHA National Advisory Council members are leaders in health and scientific disciplines (including public health and the behavioral or social sciences) relevant to the fields of alcohol, drug abuse, and mental health research. The remaining one-fourth includes leaders in public policy/relations, law, health policy, economics, and management. A further breakdown includes:

Representatives of Institutions of Higher Education (Deans, Professors, and Directors)	58%
Federal, State, and Local Governmental Officials	24%
Private Citizens & Representatives of Private Foundations	18%

TRANSFER OF STAFF TO CDC

Question. Is there any basis to the rumors about a transfer of the epidemiological staffs of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism from ADAMHA to the Centers for Disease Control?

Answer. There is continuing discussion on cooperation between CDC and ADAMHA on the epidemiology and surveillance of drug abuse and HIV infection. These discussions have centered on better defining the role of the two agencies, eliminating unnecessary duplication of effort, and clarifying specific areas of responsibility. There are existing memorandums of understanding related to these areas which are being reviewed and modified based on these discussions. There is no discussion on the transfer of staff of the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism to CDC.

Question. How would such a transfer impact data collection under the ADMS block grant?

Answer. As noted, these discussions relate to the areas of epidemiology and surveillance, not to the area of health services research, and the collection of demographic, diagnostic and outcome data related to the provision of treatment services. This type of information as well as studies of treatment effectiveness will continue to be funded with funds from the block grant set-aside and will continue to be administered by ADAMHA.

HIGH RISK YOUTH DEMONSTRATIONS

Question. The Anti-Drug Abuse Act of 1988 elevated the Office for Substance Abuse Prevention within ADAMHA to the institute level. OSAP is slated for a budget increase to $72 million and 25 new FTE positions. How many demonstration programs for high-risk youth does OSAP support?

Answer. Beginning in 1987 OSAP funded 130 innovative outreach programs targeting alcohol and other drug use among high risk youth. OSAP also anticipates awarding by the end of FY 1989, approximately 30 more high risk youth demonstration grants.

Question. What findings can you report from these demonstrations?

Answer. Results from grant program evaluations are just beginning to come into OSAP. Very promising findings have been reported about community organizing efforts in public housing projects, especially through the development of boys and girls clubs for very high risk teens in these housing projects, and the support of tenants and civic associations. Other grant programs report substantial success with programs using peer pressure to resist drugs. Such programs have also included strong involvement of parents and other adult role models. OSAP expects that more detailed and reliable findings will be reported during the next year, as the first group of demonstration grants complete their second year.

Question. How are the demonstrations evaluated?

Answer. Prior to the OSAP grant program little was known about effective prevention models that target high risk youth tested under the real world conditions. Progress in fighting the war on substance abuse was critically hindered by the absence of a consistent, comprehensive evaluation program to assess false starts and promising programs. OSAP's evaluation activities respond directly to these needs. Each of the demonstration grant programs is required to conduct process and outcome evaluations.

In addition, OSAP is conducting a major, three-year, cross-site program evaluation. Data will be derived from site visits, pilot evaluation studies, ethnographic observation, and other evaluation techniques. The results of this evaluation will provide OSAP and the field with important information about effective prevention models that have been tested under practical conditions on a high-risk youth population that includes a heavy sampling of minority youth.

AVAILABILITY OF DRUG TREATMENT PERSONNEL

Question. What is your view of the supply of personnel to provide drug treatment services? Do we have enough personnel to staff all the programs we are presently funding, and enough to fund additional programs?

Answer. There is a critical shortage of well trained substance abuse education, prevention, and treatment specialists. The significant increase recently in new programs at the local level has created a need for many new counselor positions. Programs have reported that they are trying to do more with less.

However, few colleges and universities offer established courses or a degree program in alcohol and other drug abuse prevention or counseling. Moreover, the wide range of medical, vocational, psychological, economic and social problems drug abusers bring to treatment create special needs for training. In addition, counselors turnover at a rate higher than other human service workers, in large part because of the long hours, difficult clients, and working conditions which are often physically threatening in the locations where the needs are highest--in the inner cities.

The National Training System, established by the Office for Substance Abuse Prevention during FY 1989, is intended to address this critical shortage by providing continuing education in alcohol and other drug abuse prevention and treatment courses for substance abuse counselors, health and allied health professionals, social workers, and community organization staff.

Question. How many substance abuse counselors and other alcohol and drug abuse health professionals will be trained by OSAP programs in fiscal year 1990?

Answer. The National Training system will begin operation in early FY 1990. OSAP anticipates that the system will initially

focus on developing new packages, modifying existing manuals, training trainers who can in turn train staff on a nation-wide basis, and developing collaborative relationships with associations who can assist OSAP in creating a responsive training system. The system will subsequently be expanded to increase the scope of training topics as well as the number of persons trained. During the first year it is anticipated that between 3,000-5,000 Health Professionals (physicians, nurses, social workers, and substance abuse counselors) and community-based providers will be trained. Of this total, approximately 1,000 will be substance abuse counselors.

SUICIDE PREVENTION

Question. What kinds of research do you support on the prevention of suicide, particularly among young people?

Answer. NIMH supports a wide variety of research that is directly or indirectly concerned with the prevention of suicide. The Prevention Research Branch (PRB), Division of Clinical Research, supports preventive intervention research focused on mental disorders that precede the vast majority of suicide attempts and completions. The goal is to prevent mental disorders such as depression, anxiety, and conduct disorder in children and adolescents, before a suicide attempt occurs. Furthermore, the PRB supports research on the enhancement of coping mechanisms to head off suicide attempts and completions.

Several preventive intervention studies are aimed at depression and anxiety that can lead to suicidal behavior. For example, Dr. Gerald Koocher at Boston's Children's Hospital is studying the effectiveness of a mutual support intervention for families in which a child has died; siblings of deceased children are especially at risk for emotional impairment. Dr. Karolynn Siegal at New York's Memorial Hospital for Cancer and Allied Diseases is attempting to enhance feelings of security and competence for children facing the imminent death of a parent from cancer; children whose parents have died are at risk for later emotional dysfunction.

Investigators have established that aggressive behavior is frequently associated with suicide in boys, who kill themselves three to four times more frequently than girls. Dr. Sheppard Kellam at The Johns Hopkins University is testing a preventive intervention aimed at conduct disorder in grade-school children. Similarly, Dr. Leonard Jason at DePaul University has mounted a preventive intervention study for children transferring to a new school; transfer increases the likelihood of emotional and behavioral maladjustment, as well as poor academic and social performance.

Some of the most exciting research funded by the PRB focuses on the enhancement of coping mechanisms, which will enable vulnerable individuals to see that many alternatives besides suicide exist for solving life's problems. Dr. Myrna Shure of Hahnemann University continues two decades of research on interpersonal problem-solving and prevention in Philadelphia grade-school children. Her approach has become a model emulated

throughout the nation. Dr. Nealia Bruning at Kent State University is conducting one of the first scientifically sophisticated, longitudinal studies comparing the efficacy of several stress management strategies. Dr. Robert Caplan at the University of Michigan has developed a preventive intervention strategy for unemployed adults; unemployment is known to increase the risk of emotional difficulties that may lead to suicide.

In addition to research on preventive interventions, NIMH continues to respond to the suicide issue in other research areas. NIMH support of extramural grant research in suicide has grown from eight grants and $1.0 million in FY 1986 to 12 grants and over $1.6 million in FY 1988. In FY 1989, NIMH expects to increase its support to 19 grants totalling over $3.0 million. Over $1.2 million of this amount will support studies in youth suicide. An Institute-wide Program Announcement soliciting high-quality grant applications in suicide research was released in October, 1988. The announcement includes a major emphasis on studies of suicide and suicidal behavior in youth, and on the prevention of suicide.

NIMH and the Centers for Disease Control (CDC) are the two key agencies that address the issue of suicide. NIMH worked closely with the CDC in monitoring progress toward the 1990 HHS Objective of reducing the youth suicide rate. This collaborative public health effort is continuing in the development of the Year 2000 Objectives on suicide. In another collaborative activity, NIMH is participating in the Third National Health and Nutrition Examination Survey, a major survey sponsored by Public Health Service agencies. NIMH contributed a component for the collection of data on suicidal behaviors and affective disorders in persons 15 years of age and over. The data from this survey will enable us to estimate the scope of suicide ideation and attempts in adolescents and young adults, identify targets for prevention, and followup high risk individuals.

Several useful publications on suicide and suicide prevention are being produced. NIMH has contracted for a badly-needed critical review of instruments and questionnaires currently used to assess suicidal behavior among young people. Dissemination of this review is planned. The "Report of the Secretary's Task Force on Youth Suicide", a four-volume examination of youth suicide and its prevention, is expected to be released to the public this year. A special issue of Suicide and Life-Threatening Behavior, entitled "Strategies for Studying Suicide and Suicidal Behavior" and edited by NIMH staff, was published last month. The proceedings of a workshop on "Depression and Suicide in Minorities" were published in FY 1988.

NIMH program staff continue to provide technical assistance to potential grant applicants and other researchers. In addition, NIMH plans to sponsor workshops in suicide research, with topics to include methodological issues, suicide in schizophrenia, and biological risk factors. An interactive videodisc on youth suicide was developed in collaboration with the National Library of Medicine, and is designed to be used as an educational curriculum for third and fourth year medical students. A resource guide is

being prepared for health professionals and other "gatekeepers" that deal with young people.

MENTAL HEALTH IN RURAL AREAS

Question. What research does NIMH support on the mental health problems of persons living in rural areas?

Answer. In FY 1989, the NIMH will support four research project grants and one research center grant concerned with mental health in rural areas. One research project at the University of Pittsburgh is examining the mental health service system for youth and changes in this system over time in two partly rural counties. Another project located at the University of Nebraska is using three waves of survey data and demographic information to develop a model that links local economic conditions in rural counties to depression, alcohol abuse, impairments in social roles, help seeking behavior and service utilization.

The other two research projects investigate the epidemiology of mental illness in rural contexts. A longitudinal study in psychiatric epidemiology covers nearly 3,000 adult residents in sections of Nova Scotia over a thirty year period. This study attempts to ascertain the impact of a rapidly changing environment, the degree to which such change results in disorganization at the community level, and the consequences in regard to mental disorders and use of medical/mental services. In another epidemiologic rural-urban study of child psychiatric disorders, a sample of rural children aged 6 to 11 will be compared with a previously completed urban study in Connecticut. A variety of diagnostic and behavioral questionnaires will be given to 2,220 children. Information also will be obtained from parents and teachers.

Lastly, a research center grant, recently awarded to the University of Wisconsin at Madison, is focusing on systems of care in rural and small city environments. The main activity of this Center for Research on the Organization and Financing of Care for the Severely Mentally Ill is to construct and use a core data base to address key theoretical issues in service delivery.

Question. What special mental health problems, if any, exist for residents of rural areas?

Answer. An epidemiologic study of the prevalence of nine psychiatric disorders in adults living in the Piedmont of North Carolina found that major depressive episodes and drug abuse and/or dependence were more common in the urban area, whereas alcohol abuse/dependence was more common in the rural area. Other factors such as age, sex, race and education confound simple urban/rural comparisons; when these factors are taken into account more specific differences emerge. For example, there was a higher prevalence of antisocial personality disorder in the urban area among whites compared with the rural area. Residents of rural areas also differ in having lower availability of mental health and related specialty services.

MENTAL HEALTH ISSUES FOR MINORITY POPULATIONS

Question. What does NIMH do to focus research on mental health issues critical to minority populations?

Answer. In every NIMH research announcement, the following wording is included to urge researchers to focus their research on minority populations:

Applicants for grants under the announcement are urged to give added attention (where feasible and appropriate) to the inclusion of women and racial/ethnic minorities in study populations. If minorities and women are not included in a given application, a clear rationale for their exclusion should be provided. Investigators are reminded that merely including arbitrary numbers of women and/or minority group participants in a given application is insufficient to guarantee generation of the study results.

Among other NIMH efforts to increase research on minority populations are the following:

1) Minority Mental Health Research Centers:

Currently NIMH is supporting four (4) such centers with budgets totalling $2,496,566 for FY 1988. These centers conduct research on mental health issues that are critical and specific to the four minority groups: American Indians/Alaska Natives, Asian Americans/Pacific Islanders, Blacks, and Hispanics.

An announcement has been issued recently requesting grant applications for the establishment of four additional Minority Mental Health Research Centers in FY 1990. An estimated $1 million will be added to the budget for the additional centers.

2) Minority Institutions Research Development Program:

This research development program is a new program developed in response to recommendations by minority mental health research scientists. The program is designed to increase the capacity of predominantly minority institutions and their faculty to conduct rigorous alcohol, drug abuse and mental health (ADM) research pertinent to the four minority groups. Furthermore, this program is intended to strengthen and augment the research infrastructure of the minority institutions in order to facilitate and foster the development of ADM research projects.

An announcement has been issued recently calling for applications to develop such programs. For FY 1990, the NIMH will have available approximately $1 million to support new awards for establishing these research development programs in minority institutions.

3) Research Technical Assistance Program:

The NIMH Division of Biometry and Applied Sciences has developed a program to provide systematic and intensive technical assistance for promising minority researchers interested in

pursuing mental health services research pertinent to minorities. This is a 12-month technical assistance program designed to help junior minority researchers to conceptualize and develop research proposals. For FY 1989, approximately 35 minority researchers will be selected to participate in this program.

4) Minority Regional Service Research Workshops:

During FY 1989, a series of three regional mental health services research workshops are planned for Hawaii, Texas and Washington, D.C. The purpose of these workshops is to provide a forum for researchers to share research findings and to assess the state-of-the-art of conducting mental health services research for minorities. The objective of these workshops is to stimulate and encourage the development of mental health research studies on minority populations.

MENTAL HEALTH SERVICES FOR CHILDREN AND YOUTH

Question. How do Child and Adolescent Service System Program (CASSP) grants support improvement in the availability of mental health services for children and youth? What are examples of successful programs providing case management services that have been supported under this authority?

Answer. The CASSP is a strategy development program to change the way states and counties deliver services to children and adolescents with severe emotional disturbance. Agencies that serve this population (mental health, welfare, education and juvenile justice) are encouraged to work in an integrated fashion, maximizing resources, so that children and adolescents with severe emotional disturbance are served in the most appropriate, community-based setting.

CASSP also facilitates the inclusion of families in the care of their children and in the planning of the system of care in which their children will be served. CASSP has as another goal the assurance that the system of care is sensitive to the needs of the cultural and ethnic minorities that it serves.

While CASSP does not provide for the direct funding of any service component, such as case management, the program facilitates the provision of case management in several ways. In 1986, CASSP published the monograph The System of Care for Severely Emotionally Disturbed Children and Adolescents. This document acts as a blueprint for the system of care and focuses on case management as playing a major role.

Several of the CASSP demonstrations are built around models in which State and local level coordinating committees both facilitate case management and act as arbitrators for case level disputes. Such programs are prominent in Ohio, Vermont, Maine, and recently Hawaii. County level inter-agency boards are being developed in Iowa; this type of approach is also being used in rural Georgia and Kentucky.

Other CASSP projects focus on the development of individualized care for children in the community, by using the grant funds to create mechanisms that allow the use of State and local funds for the case management that is so necessary for this intensive type of service. Projects in Alaska and Washington are good examples of this type of CASSP approach to case management.

COMMUNITY SUPPORT PROGRAMS

Question. What will happen to existing community support programs if NIMH support is phased out as you propose? What information do you have on the availability of alternative sources of financial support for such demonstration programs if Federal support is phased out?

Answer Based on previous program experience, a number of States and communities have picked up the funding for programs with demonstrated effectiveness when there are sufficient resources in the system and when there is sufficient time allowed for necessary legislative and budgetary actions.

We therefore recommend that programs approach their State Mental Health authorities for possible sources of funds in the future.

MENTAL HEALTH TRAINING NEEDS

Question. What steps are you taking to reduce the shortages of young researchers in the field of mental health? How can we encourage more young scholars to enter this important field?

Answer. The current research cadre is aging, the mean age of our investigators has been increasing. Approximately 20 percent of the agency's scientists are over the age 55 and scientists under age 36 are only half the proportion they were 8 years ago. Of particular concern is the fact that the behavioral and social sciences account for the major part of this aging effect.

We expect the following actions to have an immediate effect on encouraging young investigators to enter this research area:

1. Mental Health Academic Awards in Clinical Research

These NIMH awards are designed to facilitate the development of young psychiatrists and nurses as mental health academic researchers. These 3 year awards focus on the areas of schizophrenia, child and adolescent disorders, and the mental disorders of the aging.

2. Scientist Development Award for Clinicians (SDAC)

This new award is designed to support clinically trained (psychologists, psychiatrists, nurses, and social workers) individuals in the development of excellent research skills to bring them into full-time research careers. These awards are available in all areas of ADAMHA research including the basic, clinical and applied areas. We expect that these awards will

make it possible for many young clinically trained individuals to enter into a mental health research career. Stipend, research and career development support are provided by NIMH while the local institution provides a scientific mentor.

3.Scientist Development Award

This new ADAMHA award provides 5 years of support to highly promising developing scientists while they acquire further, new or more specialized research skills. A 3 year award is available for established investigators who wish to expand their research skills or investigators from other areas who wish to enter ADAMHA research.

4. Extramural Staff Fellowships

The NIMH has just announced a program which provides an opportunity for non-federal scientists to spend up to two years working with NIMH extramural scientists in its research support programs. These fellowships are intended to give talented scientists at an early, mid-point, or senior level in their career an opportunity to participate in and bring new ideas to the scientific research supported by the NIMH. There may also be opportunities for these fellows to collaborate with NIMH intramural scientists in clinically relevant research.

5. Outreach Programs

NIMH staff have organized workshops at professional meetings, published papers, and presented talks at universities, hospitals and professional meetings to inform the field of the research training and development opportunities offered by NIMH.

One special outreach effort that has been organized by the Schizophrenia Research Branch in NIMH; this branch has sponsored three workshops in the past year for potential schizophrenia researchers. Individuals who have applied for schizophrenia research grants which were approved but not funded have been invited to these workshops.

6. M.D./Ph.D. Fellowship

ADAMHA has just announced a new training fellowship to support potential physician/scientists through a combined medical/scientific training program which, in the long term will attract young investigators into mental health research.

7. Short Term Medical Student Training

Research training grants are awarded to medical schools to provide summer, semester, or full year research training opportunities for appropriate medical students. We feel it

will be especially helpful in drawing young investigators into mental health research.

8. Career Development Awards in Mental Health Services Research

Dr. Judd sent a special letter to the field encouraging career development applications in mental health services research to be reviewed by a committee with expertise in this area. Seventeen applications were received, including 4 from minority applicants and 7 from young psychiatrists beginning their research careers. The applications are being reviewed and some will be funded this year.

9. Public-Academic Liaison Fellowship Program in Mental Health Services Research

NlMH announced a new program to encourage research in public agencies by providing support for a training program that combines a two years of postdoctoral training in s public agency with academic training focused on research problems of concern to the public mental health agency. Joint training with at least 50% of the time in a public agency will facilitate research training that is directly relevant to the severely mentally ill served by public agencies, will increase the agency's capacity to do research, and will increase the involvement of academic centers in collaborative research with the agencies.

10. Minority Fellowship Program

NlMH announced a new Minority Fellowship Program in Psychiatry to increase the number of minority medical students, psychiatric residents, young psychiatrists pursuing research careers. Two announcements were issued for competing renewals of existing Minority Fellowship Programs in Sociology and Social Work to provide predoctoral training in areas of mental health research. These programs will be funded this year.

11. Minority Access to Research Careers Program

Three new Minority Access to Research Careers Programs were approved for funding to train honors undergraduates in minority institutions, including Native Americans, Hispanic, and Native Hawaiian students. Two Minority Access to Research Careers Faculty Fellows were funded to enable them to receive two years of advanced postdoctoral research training. A conference of Minority Honors Undergraduate students was held in Washington with papers and presentations by current and former trainees.

12. Minority Institutions Research Development Program

NIMH, NIDA, and NIAAA issued a new announcement to increase the capacity of predominantly minority institutions and their

faculty to do research in mental health, alcohol and drug abuse areas. It provides support for developing the institutions research infrastructure, for helping individual faculty members develop their research capability, and for support of individual research projects. Predominantly minority institutions have tremendous research potential, and educate a large number of potential minority researchers, but existing programs have not provided the support to fully tap in to these resources.

13. Minority Mental Health Research Centers

A new announcement was issued to establish research centers focused on the mental health problems of particular minority/ethnic groups. At present NIMH supports 4 minority research centers focusing on the mental health problems of Hispanics, Asian Americans, and Native Americans. Applications focusing on the mental health problems of American Indians/Alaska Natives, Asian Americans, Blacks, Hispanics, and/or Native Hawaiians/pacific Islanders are encouraged.

ALCOHOL ABUSE AND MINORITIES

Question. What research does NIAAA support on the alcohol abuse problems and needs of such minority populations as blacks, hispanics, Native Hawaiians, American Indians and Alaska Natives?

Answer. NIAAA supports several extramural and intramural research programs which focus on minority populations. In intramural research, one project is aimed at better understanding the dynamics of alcoholism among minority families. Through collaborative efforts with investigators at the Indian Health Service, the intramural program is also continuing research on familial alcoholism among American Indians. The extramural grant program actively encourages research on minority issues. In 1988, NIAAA supported 32 grants for approximately $4 million for research targeted to minority populations. Extramural research projects of the Homeless Demonstration Program include a significant number of minority individuals in the study population. Epidemiologic studies focus on minority populations to measure the prevalence and levels of alcohol consumption and alcohol-related social and health consequences among minority groups. Current efforts are focusing on drinking patterns and alcohol related consequences among Blacks and Hispanics. A special Minority Scholar Program is supported by NIAAA. In this program, NIAAA supports research scientists for the purpose of conducting research on minority issues and developing minority research capacity by stimulating research and serving as a resource on issues dealing with minorities and alcohol.

FLEXIBLE FREEZE

Question. Dr. Goodwin, in the budget proposal submitted by President Bush in February, the NIH was specifically identified as a priority program and the budget request was the same as what was included in the Reagan budget. It was not included in the flexible freeze category. Does the Bush budget treat the NIMH, NIDA and

NIAAA the same way as the NIH? Or are these Institutes included in the flexible freeze category?

Answer. The Bush Budget, Building a Better America, selected several programs for protection at, or increases to, the Reagan budget level. Those not mentioned are subject to the "flexible freeze." One of these protected programs was the NIH. ADAMHA's research programs were not treated the same way.

Some of ADAMHA's programs are protected in the Bush budget. Money for the homeless, for drugs, and AIDS, were excluded from the flexible freeze. For example, all of the Office for Substance Abuse Prevention and the National Institute on Drug Abuse are protected as part of the drug budget.

For ADAMHA, the main consequence of the way the Bush budget was developed is that the non-AIDS research programs of the National Institute of Mental Health and the National Institute on Alcohol Abuse and Alcoholism, are vulnerable to being cut since they are subject to the flexible freeze.

AN NIMH BUDGET OF $500 MILLION

Question. Dr. Judd, I have been informed that the NIMH could spend as much as $500 million in non-AIDS research in fiscal year 1990. Yet, the NIMH budget request for fiscal year 1990 non-AIDS spending is $361,443,000. Is that correct? If so, how would you use an increase of $138,557,000?

Answer. I can assure you that if, in this time of budgetary restraint, Congress in its wisdom were to allocate such an increase, it would be well spent. The additional funding would be used to intensify and accelerate major NIMH research initiatives concerning schizophrenia, the neurosciences, and child and adolescent disorders, among others, and to assure an ongoing, adequate supply of high-calibre researchers well-equipped to capitalize on the extraordinary growth of knowledge, technology, and opportunity in the study of mental illnesses.

Specifically, increasing the FY 90 NIMH non-AIDS research budget by approximately one-third would allow us to fund the following:

- 450 new and competing research program grants, permitting us to raise the award rate from a projected 19.8 percent to 32 percent.
- 13 new research centers focused intensively on high-priority areas of research, including the neurosciences, schizophrenia, Alzheimer's disease, suicide, and child and adolescent disorders.
- 80 more recipients of Research Scientist Development Awards, providing much-needed insurance that we will have outstanding research manpower to advance the future science of mental illness.
- A five-fold increase (from $1 million to $5 million) in support for research equipment to the field. Progress in understanding mental disorders is predicated on having the high-tech tools that can unlock the secrets of molecular genetics,

brain structure and function, and the electrochemical processes underlying emotion and thought.

- Double the number of research training stipends, which would help to both keep pace with the burgeoning field of brain science and to provide the knowledge needed to improve the diagnosis and treatment of mental disorders.

The science of mental illness is one of the fastest moving areas in all of biomedicine.

PLAN FOR SCHIZOPHRENIA AND BRAIN DISORDERS

Question. Dr. Judd, the NIMH is in the process of implementing a new combined National Plan for Research in Schizophrenia and Severe Mental Disorders. What does this plan call for?

Answer. A scientific agenda for the next decade's research focused on the major mental illnesses has been developed by the National Advisory Mental Health Council in part in response to directives issued by the Congress.

The agenda is contained in two documents: the National Plan for Research on Schizophrenia, and the National Advisory Mental Health Council Report to Congress on the Decade of the Brain.

Together, the two Reports constitute the most intensive and comprehensive analysis ever conducted in this country of scientific needs and opportunities focused exclusively on the serious mental illnesses and involving both clinical and basic research strategies.

Even though the two research plans were developed under different mandates and involved different groups of scientists, their goals are overlapping. Taken together they outline the unprecedented opportunities that exist today for applying state-of-the-art clinical and basic research strategies to the study of serious mental disorders.

The NIMH has now combined the two plans into a single scientific attack on the major mental disorders, with the Schizophrenia Research Plan emphasizing the clinical investigations and the Decade of the Brain plan providing a complementary focus on basic research--each enhancing the other in a synergistic manner.

Never before has the NIMH, the scientific community, or the advocacy field possessed two such synergistically powerful instruments for the immediate and longer-term management of our research enterprise. The National Plan for Schizophrenia Research, with its high resolution focus on the scientific demands of a baffling and tragic group of disorders which will disable some 2 million Americans during the course of their lifetimes will draw increasingly on the yield of new information gained through a vastly expanded basic and clinical neuroscientific research program such as that mapped out in the Decade of the Brain report.

PROGRESS IN IMPLEMENTING THE PLAN

Question. What progress have you made in implementing it?

Answer. Neuroscience has made remarkable scientific progress in the past two decades. In fact, 90% of what we know about normal and abnormal brain function has been discovered in the past ten years. Implementation of the Combined National Plan is progressing at a good pace, although, of course, numerous unmet opportunities remain. Highlights of progress include:

- Recent NIMH funding of four Centers for Neuroscience and Schizophrenia (at Yale University, University of Maryland, University of California at Irvine and University of Colorado.) These Centers are for the support of integrated research relevant to schizophrenia. Clinical research has generated hypotheses implicating genetic, viral, developmental, neurochemical and other biological factors in schizophrenia; basic science research is now able to test some of these as well as generate additional testable hypotheses. The scientific opportunities offered by the integration of basic and clinical approaches to better understanding the clinical symptoms, pathophysiology, and etiology of schizophrenia appear to hold great promise.

- This concept of integrating basic and clinical neuroscience approaches into research on specific diagnostic categories is being expanded into a program of Centers for Neuroscience in Mental Illness, each Center to be devoted to the examination of a specific disorder. An announcement of this program will be issued to the field in 1989.

- The recent NIMH announcement of the Diagnostic Centers for Psychiatric Linkage Studies. The NIMH is launching a broad and multifaceted initiative to study the genetics of schizophrenia, bipolar disorder, and Alzheimer's disease. The primary goal of this component of the initiative is to establish a national resource of immortalized cell lines and psychiatric histories from reliably diagnosed patients and their key relatives. Funding for the Centers will be through the NIMH Cooperative Agreement Program wherein NIMH staff serve as active scientific collaborators with investigators at the awardee institutions. It is anticipated that nine Centers will be selected during fiscal year 1989.

- The recent NIMH announcement of the Public Academic Liaison Program (PAL). This program was designed to strengthen research collaboration between research centers, especially academic research sites such as university medical centers, and the public centers responsible for the care of many severely ill patients (both children and adults), e.g., State hospital, community mental health center, or ambulatory program. Support under the PAL initiative will be through a variety of grant mechanisms. The initial receipt date for applications submitted in response to this announcement was February 1, 1989, with an anticipated award date of December 1, 1989.

- The recommendations to establish a National Neural Circuitry Data Base has been advanced by the award of a contract to the National Academy of Sciences, effective in the last quarter of FY 1989. The goal of the NAS study will be to derive a consensus among experts regarding the requirements for and the definitions of the database. The recommendations resulting

from this planning activity will be available for implementation in FY 1991.

FUNDING FOR THE PLAN

Question. What level of funding would you need in fiscal year 1990 to fully implement this plan?

Answer. Analyses of the relevant reports indicate that to fully implement the combined National Plan for Schizophrenia and Brain Research would cost $256,558,000.

Question. How much is the NIMH spending on implementing the plan in fiscal year 1989? How much is included in the budget for fiscal year 1990?

Answer. In the fiscal year 1989 budget, we estimated a total of $65,346,000 for research related to schizophrenia.

In fiscal year 1990, the NIMH is requesting $68,291,000 for research which is related to schizophrenia.

DECADE OF THE BRAIN REPORT

Question. Dr. Judd, the Committee has received the NIMH report on the Decade of the Brain which includes recommendations and plans for increasing neuroscience research during the near future. Are there accomplishments you can point to over the last few years that lead you to believe there will soon be breakthroughs in some of these areas?

Answer: Neuroscience has made remarkable scientific progress since it began as an independent discipline in the 1970s. In fact, 90% of what we know about normal and abnormal brain function has been discovered during the last ten years. During this same period, the stage was set for further progress by the identification of the molecular and the submolecular units of the central nervous system, the development of major methodological and technological innovations, and the reconceptualization of the biological bases of the major mental illnesses.

Identification of the molecular and submolecular units of the central nervous system, which includes the brain, has enabled researchers to move beyond descriptions of "the cell" to analyses of discrete molecular actions which are the biological building blocks of behavior. Development of methodological and technological innovations has dramatically extended our ability to observe the structure and functioning of the brain in living human subjects. Where the brain was once a static black box, it is now a dynamic model of blood flow, energy consumption, and structural variation. Reconceptualization of the biological bases of mental illness has focused attention on genetic predispositions, viral infections, and the interaction of the neuronal, hormonal and immunological stems.

Using molecular biology techniques and imaging technology, researchers are exploring the effect of individual psychotherapeutic drugs on specific target sites in the brain to more precisely identify sites and mechanisms of action for a wide

range of pharmacotherapies. This information is being used to design new, more effective drugs, and to further our understanding of normal and abnormal brain processes.

Brain imaging techniques also make it possible to decipher the brain's activity in living, thinking, behaving subjects. Using these techniques, it is now possible to examine subjects in various behavioral states and determine which parts of the brain are involved, or deficient, during the performance of specific mental tasks. This strategy allows the comparison of brain activity in healthy and ill subjects to decipher biochemical signatures characterizing the diverse symptoms of individual mental illnesses.

For example, direct observations of the brain made possible by today's new imaging approaches reveal that, compared to the brains of normal subjects, the brains of patients with schizophrenia contain evidence of anatomical, physiological, and neurochemical abnormalities. Among these abnormalities are enlargement of the cavities of the brain containing cerebrospinal fluid, decreased activity of the frontal lobes during cognitive activity, and actual loss of brain substance.

In addition, the imaging technique called magnetic resonance imaging, or MRI, has provided evidence that in autistic children, one small region of the cerebellum is smaller than in normal children, a probable result of inadequate development of the brain during maturation. This region is known to control many of the behaviors affected by autism. Further studies will seek that critical point in brain maturation when a toxin, virus, or injury disturbs growth in the affected region.

One of the most consistent findings about major mental illnesses is that they run in families, suggesting they are inherited. The search for genetic markers and for the defective genes through which these illnesses are transmitted has proven to be a productive area of investigation and is currently one of the most active areas of neuroscience research.

Genetic studies and studies using genetic linkage methodologies have been most promising with manic-depressive illness, schizophrenia, and Alzheimer's disease. Investigators recently identified a link between schizophrenia and an abnormality on chromosome 5 in seven families with a high incidence of this disease. This finding follows reports last year from a study involving a very large family with high incidence of manic-depressive illness. That study revealed an association between this disorder and an abnormality on chromosome 11.

These advances bring us to a position of confidence in predicting that avenues pursued by basic researchers in the 1990's will radically change diagnostic and therapeutic strategies in the 21st century.

Question. What progress is being made in implementing the recommendations in this report?

Answer. Since formulation of The Decade of the Brain Report to Congress, the Neurosciences Research Branch of the National

Institute of Mental Health has added one full time professional staff member to initiate a program of Centers for Neuroscience and Schizophrenia. This program now supports four centers designed to integrate basic and clinical neuroscience approaches into schizophrenia research.

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THE COST OF FULL FUNDING THIS REPORT

Question. What level of funding would you need in fiscal year 1990 to fully implement the report?

Answer. In fiscal year 1990, the full implementation of the recommendations contained in the Decade of the Brain Report would require an estimated $198.9 million budget within the National Institute of Mental Health. The fiscal year 1990 budget request for this activity is $143.5 million, an increase of $4.8 million, or 3.5% over the comparable amount for FY 1989.

This amount of this budget request reflects the high priority we place on this effort among all of the exciting scientific areas competing for our limited resources.

CURRENT EXPENDITURE LEVEL FOR NEUROSCIENCES

Question. How much is the NIMH spending on neuroscience research in fiscal year 1989? How much is included in the budget for fiscal year 1990?

Answer. In fiscal year 1989, estimated expenditures for neuroscience research are: Neuroscience Research Branch, $55.3 million, other related neuroscience research, $56.7 million, and

intramural neuroscience research, $26.7 million for a total of $138.7 million.

In fiscal year 1990, the budget request for neuroscience research is: Neuroscience Research Branch, $56.6 million; other related neuroscience research, $59.0 million, and intramural neuroscience research, $27.9 million for a total of $143.5 million.

INSTITUTE OF MEDICINE STUDY OF CHILD/ADOLESCENT DISORDERS

Question. Dr. Judd, I understand that NIMH has asked the Institute of Medicine to assess the status of research on child mental disorders with specific recommendations about how the NIMH might provide leadership in clinical and basic research related to mental disorders of children and adolescents. Why have you placed such a high priority on this area of research? Are there unique problems in this area which have been inadequately addressed in the past?

Answer. The serious mental health disorders of children and adolescents affect at least 7.5 million of the 63 million children under age 18. While the direct and indirect costs of these disorders are difficult to estimate, they run into the billions. These disorders keep millions of children from ever reaching their potential. The consequences in personal suffering and failure to achieve economic and productive potential are enormous. Moreover, we know that some of these disorders are risk factors for later problems: alcohol and drug abuse, suicide, and antisocial behavior.

Of course, this is a very difficult area for research. One is dealing with the developing organism and so the research models applicable to adults sometimes do not apply. In the past, the research expertise was frequently lacking. However, advances in the techniques of diagnosis and classification, genetics, the neurosciences applicable to children, and developmental psychopathology have been great. The time is ripe. We need to move ahead in this long neglected but critically important area.

PURPOSE OF THE STUDY

Question. What is your overall goal in requesting such a study?

Answer. We wanted this study to document the great need for research in the child and adolescent disorders and also to point the way. It is my sense that the time is ripe. I wanted to know the specific priorities from a large group of experts.

When you are dealing with children, there are special problems in classifying disorders, in doing epidemiology, in using imaging techniques, and even in pursuing neurochemical studies and molecular genetics. For example, in diagnosing a disorder, one must frequently combine information from a child-patient with information gathered from a parent and teacher. In epidemiological field studies it may be difficult to get reliable and valid information about children under 10 or so and these techniques are just now being developed. Certain forms of imaging such as PET are accompanied by small doses of radiation and it is

not ethical to allow this radiation to a developing organism unless the patient clearly benefits medically from the procedure as when PET is used diagnostically. Thus, PET for purely research purposes is not ethical for children. MRI has no radiation effect but requires that a patient remain perfectly still for a long time and this may be very difficult for children who are impaired. Nor can one ask a child to serve as a normal control by donating blood or spinal fluid.

My question was, can we really make progress here? The answer from the IOM was a resounding yes! They said move ahead. And they said move ahead in specific areas: epidemiology, assessment and treatment, prevention and services, and the neurosciences.

EXPENDITURES ON CHILD/ADOLESCENT DISORDERS

Question. How much is the NIMH spending for research on childhood mental disorders in FY 1989. How much is included in the fiscal year 1990 budget?

Answer. In 1989, we are spending almost $89 million for research on childhood mental disorders. About 30% of this sum is spent directly on diagnosed disorders, that is, on children or adolescents who are autistic or depressed, or hyperactive or schizophrenic, etc. The other 70% is spent on research related to the childhood disorders. This related research covers prevention, antisocial and delinquent behavior, behavior and neuroscience research related to childhood disorders, and services research and demonstration programs.

In 1990, we will spend about $27 million directly on diagnosed disorders and about $67 million on related research, for a total of $94 million.

ADAMHA STAFFING NEEDS

Dr. Goodwin, how has the increase in staff and dollars for AIDS-related activities affected the non-AIDS activities at ADAMHA? How many more FTE positions would you need to prevent allocating non-AIDS staff to AIDS activities? What was ADAMHA's original budget request to the Public Health Service for fiscal year 1990 for non-AIDS activities? How does that compare to the request before us today?

AIDS staff has increased three-fold since 1988. In that same period, the Non-AIDS FTE's decreased by five in fiscal year 1989 and then increased by 4% or 71 in fiscal year 1990. The AIDS staffing is now closer to the requirements of that program and we do not anticipate moving any more staff from non-AIDS to AIDS activities. The need to reallocate staff and resources to this critical area has slowed efforts on other programs such as the neuroimaging research being carried out by the NIMH intramural program. This is a natural consequence of priority setting.

The ADAMHA original submission to PHS requested 1836 FTE's and $1,611,275 for the fiscal year 1990 Non-AIDS budget. Congressional action on the Anti-Drug Bill increased the fiscal year 1989 budget to $1,670,000. The President's request for the fiscal year 1990 budget reflects this additional appropriation, which is not included in our initial request to PHS.

HOMELESS MENTALLY ILL CHILDREN

Question. What is your assessment of the impact of homelessness on the emotional and mental development of children? What can the NIMH do to reach these children?

Answer. Very little data currently exist on the effects of homelessness on the emotional and mental development of children. Preliminary research, however, suggests that there may be deleterious mental health, emotional, and developmental consequences of homelessness for children. For example, a study of 151 children in Massachusetts shelters has found that 47% of those children five years of age or younger exhibited at least one development lag (e.g., lags in language acquisition, social growth, motor skills) and that 33% exhibited two or more development lags. Of those children over five years of age, 50% needed further psychiatric evaluation, having exhibited signs of depression and intense anxiety. A comparison of these data with data on poor, domiciled children suggests that homelessness may be a major variable accounting for these mental health and developmental problems.

Much more research is needed, however, to guide the development of improved services for this increasingly visible population of homeless families and children. In an effort to accelerate the development of methodologically rigorous knowledge on this population, its service needs, and the adequacy and effectiveness of various service approaches for this population, the NIMH has recently announced a new initiative to encourage investigator-initiated research and research demonstrations. Among the areas encouraged for study include:

- the epidemiology of mental illness and emotional disturbance among homeless children and adolescents, and homeless families with children, including the prevalence, nature, and risk factors for mental illness and emotional disturbance;

- the service needs and service utilization of homeless families with children at risk of emotional disturbance; and

- the effectiveness, cost, and generalizability of innovative models of service delivery to this population.

The first set of grants to be funded under this announcement will be awarded by September 30, 1989.

The NIMH also is currently funding three pilot services demonstration projects for homeless children and adolescents at risk of serious emotional disturbance. Supported under the Stewart B. McKinney Homeless Assistance Act, these projects are testing innovative approaches to providing outreach and case management services to this population. Data from these projects are expected to provide a description of the population served, an assessment of the implementation of these services, and an assessment of the client, project, and system outcomes of these services.

PROTECTION AND ADVOCACY

Question. Dr. Goodwin, the fiscal year 1990 budget proposal includes a cut of $2,289,000 in the budget for the Protection and Advocacy Program for the Mentally Ill. The budget justification also states that this program will be "phased over to become an ongoing State responsibility during a 3-year period beginning in FY 1990." I understand that this is not the first time the ADAMHA budget has proposed phasing out the P&A Program. What indication do you have that the states will continue to fund this program? Why would you turn this program over to the state when it is the state run institutions that are often the very places that the p&a program is designed to monitor?"

Answer. Approximately half of the States currently provide some funding to their Protection and Advocacy (P&A) system; in fact, ten of the P&A systems are agencies within State governments, (separate from service provider agencies). The Administration feels that the federal funding to date has enabled the P&A systems to increase their staffs, to receive technical assistance from the NIMH to expand their program activities to serve mentally ill individuals, and to demonstrate their value to the States. We believe that the States will want to maintain these programs when, after three more years, they have become fully operational, and have developed trained, experienced staffs.

We have no evidence and no reason to believe that state funded P&A systems are hampered in the performance of their investigatory or monitoring duties, even when the targets are state-run institutions. As long as a P&A system is given appropriate authority, and is separated from service provider agencies, it should be able to take necessary actions against these agencies in much the same manner as State law enforcement agencies act to protect citizen rights and investigate wrongdoing throughout the State. The New York State Commission on Quality of Care, a Protection and Advocacy system funded by the State, is an outstanding example of how this can work.

CONTROLLED DRUG TRIALS

Question. Dr. Goodwin, I have had a longstanding interest in what we are doing to evaluate the effectiveness of our drug programs. What value might there be in conducting controlled trials in this area? How does that compare to evaluating ongoing treatment programs?

Answer. Clinical trials are a valuable source of scientific knowledge regarding the effectiveness of specific treatments, and may well be conducted in existing programs. The problem is in controlling sources of variance which are present in the natural environment. However, random assignment and the use of multi-site replications can provide some degree of control and help us test interventions in a systematic way. Evaluating treatment in ongoing programs where we have a mix of interventions calls for a more detailed and necessarily imperfect approach to controlling variance. Both approaches are useful and somewhat complementary. The evaluation of treatment in the natural environment can give us general information about patterns of treatment outcome, and point the way for controlled studies to test hypotheses regarding the effectiveness of specific treatments.

DECADE OF THE BRAIN REPORT

Question. Dr. Judd, the Committee has received your report on the Decade of the Brain. This report contains many recommendations and plans for increasing neuroscience research during the near future. What accomplishments can you point to over the last few years that lead you to believe there will soon be breakthroughs in some of these areas?

Answer: Neuroscience has made remarkable scientific progress since it began as an independent discipline in the 1970s. In fact, 90% of what we know about normal and abnormal brain function has been discovered during the last ten years. During this same period, the stage was set for further progress by the identification of the molecular and the submolecular units of the central nervous system, the development of major methodological and technological innovations, and the reconceptualization of the biological bases of the major mental illnesses.

Identification of the molecular and submolecular units of the central nervous system, which includes the brain, has enabled researchers to move beyond descriptions of "the cell" to analyses of discrete molecular actions which are the biological building blocks of behavior. Development of methodological and technological innovations has dramatically extended our ability to observe the structure and functioning of the brain in living human subjects. Where the brain was once a static black box, it is now a dynamic model of blood flow, energy consumption, and structural variation. Reconceptualization of the biological bases of mental illness has focused attention on genetic predispositions, viral infections, and the interaction of the neuronal, hormonal and immunological systems.

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are transmitted has proven to be a productive area of investigation and is currently one of the most active areas of neuroscience research.

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These advances bring us to a position of confidence in predicting that avenues pursued by basic researchers in the 1990's will radically change diagnostic and therapeutic strategies in the 21st century.

PROGRESS IN IMPLEMENTING RECOMMENDATIONS

Question. What progress is being made in implementing the recommendations in this report?

Answer. Since formulation of The Decade of the Brain Report to Congress, the Neurosciences Research Branch of the National Institute of Mental Health has added one full time professional staff member to initiate a program of Centers for Neuroscience and Schizophrenia. This program now supports four centers designed to integrate basic and clinical neuroscience approaches into schizophrenia research.

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THE COST OF FULL FUNDING THIS REPORT

Question. Does your budget request support the full implementation of the recommendations contained in this report?

Answer. In fiscal 1990, the full implementation of the recommendations contained in the Decade of the Brain Report would require an estimated $198.9 million budget within the National Institute of Mental Health. The fiscal year 1990 budget request for this activity is $143.5 million, an increase of $4.8 million, or 3.5% over the comparable amount for fiscal year 1989.

This amount of this budget request reflects the high priority we place on this effort among all of the exciting scientific areas competing for our limited resources.

CURRENT EXPENDITURE LEVEL FOR NEUROSCIENCES

Question. What are your expenditures for neuroscience research in fiscal year 1989 and what have you requested for this area in fiscal year 1990?

Answer. In fiscal year 1989, estimated expenditures for neuroscience research are: Neuroscience Research Branch, $55.3 million, other related neuroscience research, $56.7 million, and intramural neuroscience research, $26.7 million for a total of $138.7 million.

In fiscal year 1990, the budget request for neuroscience research is: Neuroscience Research Branch, $56.6 million; other related neuroscience research, $59.0 million, and intramural neuroscience research, $27.9 million for a total of $143.5 million.

AN NIMH BUDGET OF $500 MILLION

Question. Dr. Judd, we have been receiving phone calls and correspondence about the need for supporting a total non-AIDS research budget level for NIMH of $500 million. Now we see that your current non-AIDS research budget request is $361,443,000. Have you heard of this $500 million figure?

Answer. Yes, we have heard the $500 million figure from the field. It would represent almost a $140 million increase in the President's proposed fiscal year 1990 NIMH non-AIDS research budget.

ADDITIONAL FUNDING FOR NIMH RESEARCH

Question. Could you effectively spend that amount?

Answer. I can assure you that if, in this time of budgetary restraint, Congress in its wisdom were to allocate such an increase, it would be well spent. The additional funding would be used to intensify and accelerate major NIMH research initiatives concerning schizophrenia, the neurosciences, and child and adolescent disorders, among others, and to assure an ongoing, adequate supply of high-calibre researchers well-equipped to capitalize on the extraordinary growth of knowledge, technology, and opportunity in the study of mental illnesses.

Question. If so, for what would you use the increase?

Answer. Specifically, increasing the fiscal year 19 90 NIMH non-AIDS research budget by approximately one-third would allow us to fund the following:

- 450 new and competing research program grants, permitting us to raise the award rate from a projected 19.8 percent to 32 percent.
- 13 new research centers focused intensively on high-priority areas of research, including the neurosciences, schizophrenia, Alzheimer's disease, suicide, and child and adolescent disorders.

- 80 more recipients of Research Scientist Development Awards, providing much-needed insurance that we will have outstanding research manpower to advance the future science of mental illness.

- A five-fold increase (from $1 million to $5 million) in support for research equipment to the field. Progress in understanding mental disorders is predicated on having the high-tech tools that can unlock the secrets of molecular genetics, brain structure and function, and the electrochemical processes underlying emotion and thought.

- Double the number of research training stipends, which would help to both keep pace with the burgeoning field of brain science and to provide the knowledge needed to improve the diagnosis and treatment of mental disorders.

PLAN FOR RESEARCH IN SCHIZOPHRENIA AND BRAIN DISORDERS

Question. Dr. Judd, you are in the process of implementing a new combined National Plan for Research in Schizophrenia and Brain Disorders. Could you briefly tell us about it?

Answer. A scientific agenda for the next decade's research focused on the major mental illnesses has been developed by the National Advisory Mental Health Council in part in response to directives issued by the Congress.

The agenda is contained in two documents: the National Plan for Research on Schizophrenia, and the National Advisory Mental Health Council Report to Congress on the Decade of the Brain.

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PROGRESS IN IMPLEMENTING THE PLAN

Question. What progress have you made in implementing it?

Answer. Neuroscience has made remarkable scientific progress in the past two decades. In fact, 90% of what we know about normal and abnormal brain function has been discovered in the past ten years. Implementation of the Combined National Plan is progressing at a good pace, although, of course, numerous unmet opportunities remain. Highlights of progress include:

- Recent NIMH funding of four Centers for Neuroscience and Schizophrenia (at Yale University, University of Maryland, University of California at Irvine and University of Colorado.) These Centers are for the support of integrated research relevant to schizophrenia. Clinical research has generated hypotheses implicating genetic, viral, developmental, neurochemical and other biological factors in schizophrenia; basic science research is now able to test some of these as well as generate additional testable hypotheses. The scientific opportunities offered by the integration of basic and clinical approaches to better understanding the clinical symptoms, pathophysiology, and etiology of schizophrenia appear to hold great promise.

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FULL FUNDING FOR THE PLAN

Question. What level of funding would you need in fiscal year 1990 to fully implement this plan?

Answer. Analyses of the relevant reports indicate that to fully implement the combined National Plan for Schizophrenia and Brain Research would cost $256,558,000.

Question. What is your budget level for the schizophrenia research plan in fiscal year 1989, and what is requested for fiscal year 1990 in this budget before us?

Answer. In the fiscal year 1989 budget, we estimated a total of $65,346,000 for research related to schizophrenia.

In fiscal 1990, the NIMH is requesting $68,291,000 for research which is related to schizophrenia.

DECADE OF THE BRAIN REPORT

Question. Dr. Judd, the Committee has received your report on the Decade of the Brain. This report contains many recommendations and plans for increasing neuroscience research during the near future. What accomplishments you can point to over the last few years that lead you to believe there will soon be breakthroughs in some of these areas?

Answer. Neuroscience has made remarkable scientific progress since it began as an independent discipline in the 1970s. In fact, 90% of what we know about normal and abnormal brain function has been discovered during the last ten years. During this same period, the stage was set for further progress by the identification of the molecular and the submolecular units of the central nervous system, the development of major methodological and technological innovations, and the reconceptualization of the biological bases of the major mental illnesses.

Identification of the molecular and submolecular units of the central nervous system, which includes the brain, has enabled researchers to move beyond descriptions of "the cell" to analyses of discrete molecular actions which are the biological building blocks of behavior. Development of methodological and technological innovations has dramatically extended our ability to

observe the structure and functioning of the brain in living human subjects. Where the brain was once a static black box, it is now a dynamic model of blood flow, energy consumption, and structural variation. Reconceptualization of the biological bases of mental illness has focused attention on genetic predispositions, viral infections, and the interaction of the neuronal, hormonal and immunological systems.

Using molecular biology techniques and imaging technology, researchers are exploring the effect of individual psychotherapeutic drugs on specific target sites in the brain to more precisely identify sites and mechanisms of action for a wide range of pharmacotherapies. This information is being used to design new, more effective drugs, and to further our understanding of normal and abnormal brain processes.

Brain imaging techniques also make it possible to decipher the brain's activity in living, thinking, behaving subjects. Using these techniques, it is now possible to examine subjects in various behavioral states and determine which parts of the brain are involved, or deficient, during the performance of specific mental tasks. This strategy allows the comparison of brain activity in healthy and ill subjects to decipher biochemical signatures characterizing the diverse symptoms of individual mental illnesses.

For example, direct observations of the brain made possible by today's new imaging approaches reveal that, compared to the brains of normal subjects, the brains of patients with schizophrenia contain evidence of anatomical, physiological, and neurochemical abnormalities. Among these abnormalities are enlargement of the cavities of the brain containing cerebrospinal fluid, decreased activity of the frontal lobes during cognitive activity, and actual loss of brain substance.

In addition, the imaging technique called magnetic resonance imaging, or MRI, has provided evidence that in autistic children, one small region of the cerebellum is smaller than in normal children, a probable result of inadequate development of the brain during maturation. This region is known to control many of the behaviors affected by autism. Further studies will seek that critical point in brain maturation when a toxin, virus, or injury disturbs growth in the affected region.

One of the most consistent findings about major mental illnesses is that they run in families, suggesting they are inherited. The search for genetic markers and for the defective genes through which these illnesses are transmitted has proven to be a productive area of investigation and is currently one of the most active areas of neuroscience research.

Genetic studies and studies using genetic linkage methodologies have been most promising with manic-depressive illness, schizophrenia, and Alzheimer's disease. Investigators recently identified a link between schizophrenia and an abnormality on chromosome 5 in seven families with a high incidence of this disease. This finding follows reports last year from a study involving a very large family with high incidence of manic-

depressive illness. That study revealed an association between this disorder and an abnormality on chromosome 11.

These advances bring us to a position of confidence in predicting that avenues pursued by basic researchers in the 1990's will radically change diagnostic and therapeutic strategies in the 21st century.

PROGRESS IN IMPLEMENTING RECOMMENDATIONS

Question. What progress is being made in implementing the recommendations in this report?

Answer. Since formulation of The Decade of the Brain Report to Congress, the Neurosciences Research Branch of the National Institute of Mental Health has added one full time professional staff member to initiate a program of Centers for Neuroscience and Schizophrenia. This program now supports four centers designed to integrate basic and clinical neuroscience approaches into schizophrenia research.

This concept of integrating basic and clinical neuroscience approaches into research on specific diagnostic categories is being expanded into a program of centers for Neuroscience in Mental Illness, each Center to be devoted to the examination of a specific disorder. An announcement of this program will be issued to the field in 1989.

Also ready for distribution to the field is a research announcement establishing Centers for Excellence in Molecular Neurobiology. These centers will seek to advance the application of significant new experimental strategies in molecular neurobiology to research on mental health problems.

In fiscal year 1989, a program announcement was issued to the field in the area of Mathematical/Computational/Theoretical Neuroscience. An overwhelming response was received, and applications submitted in February of this year will be eligible for funding in December 1989.

The recommendation to establish a National Neural Circuitry Data Base has been advanced by the award of a contract to the National Academy of Sciences, effective in the last quarter of fiscal year 1989. The goal of the NAS study will be to derive a consensus among experts regarding the requirements for and the definitions of the database. The recommendations resulting from this planning activity will be available for implementation in fiscal year 1991.

THE COST OF FULL FUNDING THIS REPORT

Question. What level of funding would you need in fiscal year 1990 to fully implement this report?

Answer. In fiscal year 1990, the full implementation of the recommendations contained in the Decade of the Brain Report would require an estimated $198.9 million budget within the National Institute of Mental Health. The FY 1990 budget request for this

activity is $143.5 million, an increase of $4.8 million, or 3.5% over the comparable amount for fiscal year 1989.

This amount of this budget request reflects the high priority we place on this effort among all of the exciting scientific areas competing for our limited resources.

CURRENT EXPENDITURE LEVEL FOR NEUROSCIENCES

Question. What are your expenditures for neuroscience research in fiscal year 1989 and what level of funding is requested in the budget request for fiscal year 1990?

Answer. In fiscal year 1989, estimated expenditures for neuroscience research are: Neuroscience Research Branch, $55.3 million, other related neuroscience research, $56.7 million, and intramural neuroscience research, $26.7 million for a total of $138.7 million.

In fiscal year 1990, the budget request for neuroscience research is: Neuroscience Research Branch, $56.6 million; other related neuroscience research, $59.0 million, and intramural neuroscience research, $27.9 million for a total of $143.5 million.

INSTITUTE OF MEDICINE STUDY OF CHILD/ADOLESCENT DISORDERS

Question. Dr. Judd, we understand that NIMH has asked the Institute of Medicine to assess the status of research on child mental disorders with specific recommendations about how the institute might provide vigorous leadership in clinical and basic research related to mental disorders of children and adolescents. Why have you placed such a high priority on this area of research? Are there unique problems in this area which have been inadequately addressed in the past?

Answer. The serious mental health disorders of children and adolescents affect at least 7.5 million of the 63 million children under age 18. While the direct and indirect costs of these disorders are difficult to estimate, they run into the billions. These disorders keep millions of children from ever reaching their potential. The consequences in personal suffering and failure to achieve economic and productive potential are enormous. Moreover, we know that some of these disorders are risk factors for later problems: alcohol and drug abuse, suicide, and antisocial behavior.

Of course, this is a very difficult area for research. One is dealing with the developing organism and so the research models applicable to adults sometimes do not apply. In the past, the research expertise was frequently lacking. However, advances in the techniques of diagnosis and classification, genetics, the neurosciences applicable to children, and developmental psychopathology have been great. The time is ripe. We need to move ahead in this long neglected but critically important area.

INSTITUTE OF MEDICINE STUDY OF CHILD/ADOLESCENT DISORDERS

Question. What is your overall goal in requesting such a study?

Answer. We wanted this study to document the great need for research in the child and adolescent disorders and also to point the way. It is my sense that the time is ripe. I wanted to know the specific priorities from a large group of experts.

When you are dealing with children, there are special problems in classifying disorders, in doing epidemiology, in using imaging techniques, and even in pursuing neurochemical studies and molecular genetics. For example, in diagnosing a disorder, one must frequently combine information from a child-patient with information gathered from a parent and teacher. In epidemiological field studies it may be difficult to get reliable and valid information about children under 10 or so and these techniques are just now being developed. Certain forms of imaging such as PET are accompanied by small doses of radiation and it is not ethical to allow this radiation to a developing organism unless the patient clearly benefits medically from the procedure as when PET is used diagnostically. Thus, PET for purely research purposes is not ethical for children. MRI has no radiation effect but requires that a patient remain perfectly still for a long time and this may be very difficult for children who are impaired. Nor can one ask a child to serve as a normal control by donating blood or spinal fluid.

My question was, can we really make progress here? The answer from the IOM was a resounding yes! They said move ahead. And they said move ahead in specific areas: epidemiology, assessment and treatment, prevention and services, and the neurosciences.

EXPENDITURES ON CHILD/ADOLESCENT DISORDERS

Question. How much are you spending for research on childhood mental disorders in fiscal year 1989, and how much is contained in the fiscal year 1990 budget for these activities?

Answer. In fiscal year 1989, we are spending almost $89 million for research on childhood mental disorders. About 30% of this sum is spent directly on diagnosed disorders, that is, on children or adolescents who are autistic or depressed, or hyperactive or schizophrenic, etc. The other 70% is spent on research related to the childhood disorders. This related research covers prevention, antisocial and delinquent behavior, behavior and neuroscience research related to childhood disorders, and services research and demonstration programs.

In fiscal year 1990, we will spend about $27 million directly on diagnosed disorders and about $67 million on related research, for a total of $94 million.

OSAP NATIONAL TRAINING SYSTEM

Question. How is the Office for Substance Abuse Prevention implementing its $5 million national training system? Are these funds sufficient to develop a national training program for both prevention and treatment personnel as the legislation mandates?

Answer. As you indicate, the Anti-Drug Abuse Act of 1988 specified that $5.0 million of appropriated funds be used for substance abuse clinical training programs and medical education training. The OSAP was

provided $3.0 million to initiate a National Training System which will provide continuing education in alcohol and other drug abuse education courses for substance abuse counselors, health professionals, social workers, and community organization staff. The remaining $2.0 million provides support for an Alcohol/Drug Health Professions Education program jointly sponsored by NIAAA and NIDA. This program focuses on the development and implementation of curriculum and effective training models for health professions institutions.

Development of the National Training System is currently underway. The system will initially concentrate on the development of training packages and collaboration with existing support systems. The system will subsequently expand both the scope of the training topics and the number of persons to be trained. OSAP believes the funding provided is sufficient to begin meeting the training needs of the numerous alcohol and other drug abuse counselors as well as a large number of prevention workers doing community education in programs nationally.

INSTITUTE LEVEL STATUS FOR OSAP

Question. The 1988 drug bill raised OSAP to Institute-level status. What progress has ADAMHA made in establishing OSAP as an Institute-level organization? What is the projected completion date?

Answer. OSAP has submitted to the Department a request for reorganization as a separate organizational entity equivalent to the existing Institutes, as required by the Anti-Drug Abuse Act of 1988. At this organizational level OSAP will require changes in its functional mandates to include grant and contract review and management and finance offices, provide program monitoring for the new model projects for pregnant and postpartum women and their infants, manage a new State prevention demonstration program, manage a new national training program, and develop comprehensive prevention strategies. Formal approval is anticipated by summer, 1989.

PROPOSED OSAP FUNDING

Question. What is the level of funding proposed for each of OSAP's three existing grant programs in fiscal year 1990?

Answer. The funding levels are as follows:

High Risk Youth Grants	--	$19.9 million
Pregnant Addicts Grants	--	$ 4.2 million
State Prevention Grants	--	$15.0 million

In addition to these grant programs, President Bush has proposed a new grant program entitled the "Community Partnership Grants for Drug Abuse Prevention and Treatment." This program will provide OSAP $35 million in FY 1990 to support grants to about 150 communities to initiate the formation of public/private sector partnerships which will develop programs for substance abuse prevention and treatment.

Question. Is this sufficient?

Answer. The request provides sufficient funding to enhance the OSAP program efforts. The funds requested will provide new grants within both the High Risk Youth and the Pregnant Addicts grant programs and maintain the Community Youth program at the same level of effort as in FY 1989.

Question. How many requests for grant applications has the organization received to date for fiscal year 1989 funding?

Answer. Applications for the new grant programs in fiscal year 1989 are not due until May 15, 1989. However, our estimates of applications to be received by this date are as follows:

High Risk Youth -- 1,000
Pregnant and Postpartum Women and Their Infants --500
Conference Grants -- 150

OSAP ACCOMPLISHMENTS

Question. What do you believe have been the most significant accomplishments in the two year history of OSAP?

Answer. Some of the significant OSAP accomplishments over the past two years include:

- The awarding of 130 High Risk Youth demonstration grants. In its first year of operation alone, the High Risk Youth program directly served over 27,000 young people and 6,800 family members; OSAP grantees provided educational programs for schools and community groups that reached an additional 91,000 persons, including substantial involvement with training service providers and key community leaders. Also during the first year, OSAP grantees trained more than 17,000 individuals and designed 287 new training, treatment, and assessment instruments.

- The provision of national leadership and focus to community-based alcohol and other drug prevention programs through the development of linkages with national organizations serving youth and multicultural populations;

- The establishment of the Learning Community on High-Risk Youth. This is a consortium of grantees, researchers, government representatives, service providers, and others working in the areas of high-risk youth. The Learning Community members come together to develop, share, and implement new knowledge and effective strategies in the prevention of alcohol and other drug use among high-risk youth as well as in the treatment and rehabilitation of such youth.

- The establishment of the National Clearinghouse for Alcohol and Drug Information (NCADI) which responds to more than 100,000 inquiries a year with more than 5 million pieces of alcohol and other drug abuse literature targeted to scientists, policy makers, program administrators, State and local governments, national voluntary and professional associations, social/health/juvenile justice service providers, the media, and the general public.

- As part of the Clearinghouse operations, the establishment of the Regional Alcohol and Drug Awareness Resource (RADAR) Network, which is comprised of more than 80 sites of information resources in the States and among national and international organizations.

- Delivery of on-site technical assistance and support to over 167 organizations in 41 states.

- The sponsoring of approximately 83 conferences and workshops which have targeted youths, communities, parents, and parent groups, schools, multicultural populations, the elderly, disabled populations, and national and State organizations. OSAP also conducted five regional training workshops on prevention for representatives of national youth serving organizations, and eight regional training workshops for multicultural participants.

Finally, OSAP conducted five regional communications workshops to provide training for state and local prevention staff and volunteers.

- The development or support for several national public education campaigns, including the "BE SMART! STAY SMART! DON'T START!" program aimed initially at 8- to 12- year olds but to continue through the next 10 years; "COCAINE. THE BIG LIE." in conjunction with the National Institute on Drug Abuse, which will be followed with a new campaign entitled "CRACK. THE BIG LIE." aimed at inner-city African American/Black youth. And, support for public education efforts connected with National Alcohol-Related Birth Defects Week; Drug-Free America Week; and National Drunk and Drugged Driving Awareness Week.

DEMONSTRATIONS FOR THE DISADVANTAGED

Question. How has the knowledge generated by the research institutes contributed to OSAP's demonstration program, in particular, helped to guide prevention and intervention approaches for the economically disadvantaged, inner city youth, and programs for rural areas?

Answer. To the extent possible, the results of studies supported by the research institutes are being used by OSAP in the development of prevention and intervention approaches to reverse the drug epidemic affecting disadvantaged inner city and rural youth. Unfortunately however, most prevention research conducted by the Institutes has focused on relatively lower risk white, middle-class youth who are in schools while the OSAP programs focus on high risk youth, including those who are school drop-outs or are at risk of dropping out of school.

In recognizing the difficulties of conducting controlled prevention evaluation research in practical community settings, OSAP has supported efforts to move the substance abuse prevention field towards empirically-based tests of promising prevention programs. In addition, OSAP has developed a network of applied prevention and intervention practitioners, researchers, advocacy organizations, and public policy officials at all levels of government into the OSAP High Risk Youth Learning Community. This network provides a means for rapidly identifying implementation problems and disseminating promising findings. Within the Learning Community are eight smaller networks or interest groups that focus on different facets of prevention/intervention service delivery for high risk youth:

- Rural programs
- Inner city program
- School-based and drop-out prevention programs
- Juvenile justice system programs
- Programs serving youths 0 to 5 and their parents
- Programs serving children of substance abusers
- Family and parent based programs
- Early intervention programs for youth already using alcohol and other drugs

In addition, the Learning Community has active ethnic caucuses of Black, Hispanic, Asian/Pacific Islander, and Native American/Alaskan Native prevention practitioners. Through the Learning Community, the smaller networks and caucuses, and the range of program evaluations being conducted, OSAP expects to generate and share innovative and effective solutions to substance abuse prevention problems, and to promote rapid sharing of new knowledge, and to assure maximum utilization of the most effective practices and approaches to working with high risk youth.

OSAP AS A PROPORTION OF THE ADAMHA BUDGET

Question. What is OSAP's percentage of funding in the total ADAMHA proposed budget for fiscal year 1990?

Answer. The OSAP request for $107 million is approximately 6.1% of the total ADAMHA fiscal year 1990 request of $1.6 million.

Question. In light of its important role in the drug abuse effort, does this represent an appropriate level of funding?

Answer. The Bush Administration has proposed an additional $35 million for the OSAP prevention programs in fiscal year 1990. This proposal, coupled with OSAP's current request, would provide a total funding level of $107.3 million in FY 1990, an approximate 50% increase over OSAP's FY 1989 funding level. We believe this level of funding provides OSAP the resources necessary to meet its mandated responsibilities in developing and implementing effective prevention programs.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF JOHN H. KELSO, ACTING ADMINISTRATOR, HEALTH RESOURCES AND SERVICES ADMINISTRATION

ACCOMPANIED BY:

JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT

DR. DANIEL F. WHITESIDE, DIRECTOR, BUREAU OF MATERNAL AND CHILD HEALTH AND RESOURCES DEVELOPMENT

DR. EDWARD D. MARTIN, DIRECTOR, BUREAU OF HEALTH CARE DELIVERY AND ASSISTANCE

DR. J. JARRETT CLINTON, DIRECTOR, BUREAU OF HEALTH PROFESSIONS

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, OFFICE OF THE SECRETARY

JEFFREY HUMAN, DIRECTOR, OFFICE OF RURAL HEALTH POLICY

BUDGET REQUEST

Senator HARKIN. The subcommittee will resume its sitting. Our next witness will be John Kelso, Acting Administrator of the Health Resources and Services Administration. I am particularly pleased to have you here today. I have learned that you are from Iowa.

Mr. KELSO. Yes, sir.

Senator HARKIN. There must be a big love in here of Iowans today. Maybe we will be able to communicate a little bit better.

Mr. KELSO. I'm sure we will.

OPENING STATEMENT

Senator HARKIN. The proposed budget for HRSA is a cause for concern. Except for increases for the homeless under the McKinney Act, which the President has pledged to fund at the fully authorized level, the request gives us pause for concern—health professions and nursing education programs are zeroed out, and straight line funding for critical primary care programs like the Community and Migrant Health Centers and Maternal and Child Health Block Grant.

These programs serve the basic needs of the poor in our society. They have been making do for the past several years, doing more with less as the demand grows and funding hasn't kept pace. We need to know the impact of these proposed cuts in human terms, how many of those currently served lose their services, and how many people won't even get a chance of service.

PREPARED STATEMENT

Mr. Kelso, your statement will be placed in the record in full. If you would please introduce your colleagues here and proceed with your remarks, I'd appreciate it.

[The statement follows:]

STATEMENT OF JOHN H. KELSO

I am pleased to appear before you today to discuss the fiscal year 1990 budget request for the Health Resources and Services Administration.

President Bush's FY 1990 budget for the Health Resources and Services Administration includes a number of initiatives. These include HRSA Administration's portion of a 24 percent increase for PHS HIV activities, which are requested in a consolidated HIV request in the Office of the Assistant Secretary for Health, and full funding for the McKinney Homeless Assistance Act, which means a 330 percent increase over FY 1989 for the health care for the homeless grants administered by HRSA. The Administration has indicated that President Reagan's FY 1990 budget for programs within the residual freeze category, such as the balance of HRSA's activities, is one starting point for the Congressional Budget process.

The programs of the Health Resources and Services Administration span a wide range of activities. They provide grants or support for personal health services to numerous special populations that aid in improving the education, supply, distribution, and quality of the Nation's health professionals; and they provide technical assistance to enhance the utilization of the nation's health resources and facilities to support these efforts. In Fiscal year 1990, we are requesting approximately $1.2 billion and 1,498 full-time-equivalent positions.

HRSA's clients are mothers and children; the poor; the medically underserved; migrant workers; health professions students; persons

with AIDS, chronic lung disease and Hansen's disease; those in need of organ transplants; the homeless; and those who are too sick to leave their homes.

Since 1982, when the Health Resources and Services Administration was formed, its mission has continued to rapidly adapt to a changing environment. While our agency's essential focus has remained ensuring health services to persons who might not otherwise receive care, the agency has developed new and innovative approaches to providing that care, and at the same time accepted responsibility for new programs addressing current public health needs.

Direct Health Care Services

Our FY 1990 budget requests over $460 million for Community Health Centers, Migrant Health Centers, and Black Lung Clinics.

The agency's 1990 budget proposal will continue to foster State and Federal partnerships for the provision of direct health care services. This strategy recognizes the role that States can and do have with regard to generating resources and revenues needed by the community and migrant health centers.

Infant Mortality

In 1990 we are expanding the Infant Mortality Prevention Initiative to $32 million, an increase of $11 million above the 1989 appropriation. This request will support an additional 40 to 70 community and migrant health centers providing case managed services to between 60,000 and 75,000 high-risk pregnant women. It also will

expand overall perinatal capacity in community and migrant health centers to approximately 175,000 pregnant women per year. This will be accomplished through a proven case-managed, comprehensive approach that will focus on the coordination of appropriate services throughout the highrisk mother's child bearing years.

Maternal and Child Health

The Maternal and Child Health block grant allocates funds to States to provide a wide range of health services to mothers and children, including preventive and primary care and rehabilitative services. Our 1990 request for $554 million is the same as the 1989 appropriation. As in past years, up to 15 percent of these funds will be for special projects of regional and national significance (SPRANS) in the categories of research, training, hemophilia, genetic diseases, and maternal and child health improvement.

National Health Service Corps and Loan Repayments

The budget request for the National Health Service Corps is $20 million in 1990. This level will fund only obligors in 1990. It is imperative that scarce resources previously devoted to other federally supported NHSC activities be diverted to programs that have a higher priority within the Administration's health services plans.

The National Health Service Corps Amendments of 1987 authorized loan repayments in exchange for service in an underserved area. In 1988 we initiated the National and State Loan Repayment programs and expanded them to $8 million in 1989 and another $8 million in 1990

for a State loan repayment program. These programs will recruit health professionals in needed specialties as these individuals are completing their training and are ready to begin fulfilling their obligation. These individuals will agree to serve in health manpower shortage areas in exchange for repayment of a portion of loans incurred to pay the cost of their medical education.

Homeless

The 1990 budget provides $64 million for health care to the homeless, an increase of $49 over the 1989 level. This request will support a broad range of primary care, alcohol and substance abuse, and mental health services to approximately 600,000 homeless individuals in approximately 150 health care for the homeless programs. Emphasis will be placed on providing preventive as well as curative services to a broad sector of the homeless including runaway adolescents, homeless pregnant women and children, and individuals with chronic substance abuse and mental health problems. Grants will be made to applicants demonstrating broad community participation and linkages with other community providers of critical support needs of the homeless.

Health Professions

At the end of fiscal year 1989 the investment in Health Professions will total nearly $9 billion. This investment has increased the supply of health professionals; and, beginning in the late 1970's and through the 1980's, in addressing more targeted objectives such as primary care, disadvantaged assistance, improvement in advanced and specialized nurse training.

In recognition of these successes in programs where alternative sources are somewhat more available and where concerns are somewhat less pressing, plus the Department's increased fiscal constraints, the Administration proposes discontinuation of health professions education subsidies in fiscal year 1990. The Department is targeting limited Federal resources to other priorities such as AIDS, biomedical research, and alcohol and drug abuse.

The Health Resources and Services Administration will continue to administer the health professions and nursing revolving loan funds which will make available approximately $86 million for loans to about 32,500 students. The budget also includes $100 million in loan guarantee authority for the HEAL program to support 10,000 health professions student borrowers.

National Practitioner Data Bank

The Health Care Quality Improvement Act of 1986 authorized the establishment of a national practitioner data bank. On December 30, 1988, HRSA awarded a multi-phased contract to establish the data bank. This data bank will be used for the receipt, storage, and dissemination of information on paid medical malpractice judgments and settlements, sanctions taken by licensing authorities, losses of membership in professional societies, and certain professional review actions taken by health care entities.

No funds are requested in 1990 for this activity. An estimated $2 million in user fees to be collected in 1990 will continue funding the two objectives of the first phase of the contract. One objective is to develop a system to monitor and assess compliance

with the reporting requirements of the law and to report instances of noncompliance to the Secretary and to the Office of the Inspector General for field investigations. The other is to prepare required reports to the Congress.

Organ Transplantation

The public perception of equity and fairness in the allocation of organs for transplantation has improved with the establishment of the national Organ Procurement and Transplantation Network. The network has also resulted in an increased number of available organs. Our 1990 budget request of $2 million will continue support of the network. The funds also will support the scientific registry which is used to track the scientific and clinical status of organ recipients.

Rural Health

The budget request includes $3 million for the Office of Rural Health Policy to fund a total of 7 Rural Health Policy/Research Centers. These centers will provide an information base and a policy research capability on a wide range of rural health concerns including access to care, financing systems, alternative delivery systems and occupational health issues.

Cross Cutting/New Initiatives

As new problems rise in the health care area, HRSA is often the agency which assumes responsibility to deal with them. Our 1990

budget request includes several initiatives designed to provide a timely response to new and significant health issues:

- The National Childhood Vaccine Injury Act of 1986 established a program to provide compensation for vaccine-related injury or death. In 1990 HRSA will maintain the fiscal records of the claims trust fund and offer required medical advise to the court. The 1990 HRSA budget estimates obligations of $132 million for claim payments and other costs to be disbursed from the Vaccine Compensation Trust Fund.
- Although funding is provided to a central PHS account, our AIDS activities continue to be an important part of the battle to control this dreaded disease. In 1990, this agency is asking for a total of $56 million for AIDS projects. The total will be used as follows:
  - $18.8 million to continue the service demonstration projects in communities with a high incidence of AIDS;
  - $7.9 million to carry on the pediatric demonstration projects started in 1988;
  - $14.8 million to expand the Education and Training Centers set up to instruct health care and related providers in the care, treatment, and support of AIDS sufferers; continued emphasis for curriculum development on AIDS in our nation's health professions and nurse training institutions;
  - $10.9 million to begin a new initiative which will provide care for persons with the AIDS/HIV infection in community health centers, that may ultimately help to relieve the increasing burden on inpatient and long term care public facilities while improving efforts to mainstream the care for this population into the general health care system; and

- $4.0 for AIDS facilities renovation grants to support construction/renovation projects in nonacute intermediate and long-term care facilities.

In conclusion I can assure the members that we at HRSA see the coming year as one with many opportunities and numerous challenges, and we are looking forward to working with you in meeting and solving both.

Mr. Chairman and members of the Committee, my associates and I will be pleased to answer any questions you may have on the specifics of this budget request.

BIOGRAPHY OF JOHN H. KELSO

Position: Deputy Administrator
Health Resources and Services Administration
U.S. Public Health Service
Department of Health and Human Services

BIRTHPLACE AND DATE: Iowa City, Iowa, June 16, 1925

EDUCATION: B.A. - 1949 and M.A. - 1950, University of Iowa

EMPLOYMENT BACKGROUND:

10/1/88 to PRESENT:		Acting Administrator, Health Resources & Services Administration
8/19/86 - 9/88	-	Deputy Administrator Health Resources & Services Administration
6/29/85 - 8/19/86	-	Acting Administrator Health Resources & Services Administration
9/82 - 6/28/85	-	Deputy Administrator Health Resources & Services Administration
1/81 - 9/82	-	Acting Administrator Health Services Administration
1976 - 1982	-	Deputy Administrator Health Services Administration

1973 - 1976 - Director, Office of Regional Operations
Office of the Assistant Secretary for Health
DHEW

1971 - 1973 - Associate Administrator for Management, Health Services and Mental Health Administration, DHEW

1968 - 1971 - Assistant Administrator for Management, Health Services and Mental Health Administration, DHEW

1966 - 1968 - Executive Officer, Public Health Service, DHEW

1962 - 1966 - Assistant Executive Officer, BSS/Environmental Health, PHS, DHEW

1960 - 1962 - Chief, Management Advisory Branch, BSS/EH, PHS, DHEW

1957 - 1960 - Management Analyst, PHS, DHEW

1955 - 1957 - Management Analyst, Department of Agriculture

1951 - 1955 - Occupational Research Analyst, Department of the Navy

INTRODUCTION OF ASSOCIATES

Mr. KELSO. On the far end is Dennis Williams, Deputy Assistant Secretary for Budget. Next to him is Jeffrey Human, who is the Director of our Office of Rural Health Policy; Dr. Jarrett Clinton, who is the Director of the Bureau of Health Professions; James Walsh, who is the Associate Administrator for Operations and Management. On my right is Dr. Martin, who is the Director of the Bureau of Health Care Delivery and Assistance. Then there is Dr. Whiteside, who is the Director of the Bureau of Maternal and Child Health and Resources Development.

I have a brief synopsis, Mr. Chairman, that I will get through quickly.

Senator HARKIN. That would be fine.

Mr. KELSO. Mr. Chairman, the fiscal year 1990 budget for the Health Resources and Services Administration would, first, fund our infant mortality initiative at the 1990 authorization level of $32 million. This represents a greater than 50-percent increase over the fiscal year 1989 appropriation level, and will reach an additional 19,000 high risk mothers-to-be.

Second, it will provide health care for the homeless at a funding level more than $45 million greater than this year's level.

Third, it will make available approximately $485 million for health care services. These services will be delivered through HRSA's programs for community and migrant health centers, and black lung and Hansen's disease patients. This request will maintain the fiscal year 1989 appropriation level.

Fourth, it will continue to fund the MCH block grant at over $550 million, the same as this year's level.

Fifth, it will provide sufficient staff support to complete work on the first phase of the National Practitioner Data Bank and allow us to continue the work we began this year on the vaccine compensation program.

The consolidated AIDS request in the Office of the Assistant Secretary for Health, which I understand you heard last Friday, proposes a 24-percent increase for HRSA's AIDS programs. This level will provide some increase over this year's efforts to train health professionals on the treatment and diagnosis of AIDS patients through our education and training center grants. It will provide an inflationary increase over this year's grants to service demonstration sites, including pediatric demonstrations in the development of comprehensive and cost effective methods for the treatment of AIDS patients. It will maintain this year's construction/renovation grants for the nonacute care facilities for AIDS patients. And, sixth, it will initiate a $10.9 million program to provide primary care services to AIDS patients at community health centers.

Finally, I should note that in these times of fiscal constraint, it was necessary to reduce some current funding levels to achieve budget savings and the increases I have just mentioned. As you have already noted, the most prominent decrease is in health professions. These programs have received Federal funding for over 15 years and have been highly successful in increasing the supply of health professionals. In view of this and because of our efforts over the past 2 decades in improving primary care and the geographic distribution of health care providers, these funds have been targeted to other more pressing health care programs.

At this time, Mr. Chairman, my colleagues and I will be pleased to respond to your questions.

HEALTH PROFESSIONS

Senator HARKIN. Thank you very much for that concise statement, Mr. Kelso.

In the interest of time, I have just got a few questions I want to get on the record. One obviously has to do with the health professions education.

Mr. KELSO. Right.

Senator HARKIN. Let me talk about in terms of just rural areas. Rural communities average 53 doctors for every 10,000 people, while the national average is 163 doctors for 10,000 people. There are now today 34 million Americans living in designated health manpower shortage areas where there is just one doctor to every 3,500 people. According to HRSA's calculations, it would take 4,500 primary care doctors in those areas to remove the underserved designation.

Yet, this budget has proposed eliminating just about every dime of assistance to individuals and institutions for training in health care, including for areas suffering critical shortages of primary care doctors, nurses, and others.

Can you tell us why the health professions education funds have been eliminated?

Mr. KELSO. As I said in my statement, it is a reflection of the budget constraints and the fact that these programs have been around for many years. In the aggregate there is an adequate supply of health professionals.

I think the problem you are dealing with is where they are. Where is the distribution? That gets us into the National Health Service Corps which is a program cited for reduction in 1990.

When we put this budget together, the assumption we made was that with the increasing supply of physicians there would be more of a tendency for them to locate in underserved areas.

Second, we recently received authority for the loan repayment program. This is a Federal-State program which was Federal-State for the last 2 years. The budget before you is State only.

I would have to tell you that our experience in terms of doctors voluntarily going to some of these underserved areas isn't what we thought it would be.

The loan repayment program, particularly as it relates to the States, has not really produced that many health professionals who can be directed into underserved areas. Therefore, we think we have a problem, and we may have to back off and take another look at this situation.

Senator HARKIN. This is where you pay back——

Mr. KELSO. Yes.

Senator HARKIN [continuing]. A portion or all of the loan.

Mr. KELSO. If you have an outstanding loan, under the State program, the State would forgive a certain amount of the loan. The Federal Government would pay for 75 percent, up to $20,000, in turn for 1 year of service.

It is a takeoff from the National Health Service Corps scholarship program which we had through the 1970's and into the early part of the 1980's.

NATIONAL HEALTH SERVICE CORPS SCHOLARSHIPS

Senator HARKIN. We have no more money for the National Health Service Corps scholarships? When was that——

Mr. KELSO. Funds have not been requested by the administration since about 1981, but the Congress has provided small amounts except for last year.

LOAN REPAYMENT

Senator HARKIN. Now, tell me again about the loan repayment program. That has been a Federal function. Right?

Mr. KELSO. It is State and Federal. For the first 2 years, both the Federal Government and the State government participated in the program. The budget before you limits the program to only a State activity.

Senator HARKIN. Why is that?

Mr. KELSO. The administration feels that the States better know where their underserved areas are, and therefore, it should be a State responsibility.

Senator HARKIN. But if this is the repayment, I mean, this is giving incentives——

Mr. KELSO. Yes; it is.

Senator HARKIN [continuing]. To people to go to rural areas. This is a national problem I assume. It is not just a State problem. It's a national problem.

Mr. KELSO. In the latter part of 1988, we made seven awards to States. As of this moment, the most recent data we have, the States have made no commitments. So, it has not really been all that successful to date.

Senator HARKIN. The State program has not been all that successful.

Mr. KELSO. Right.

Senator HARKIN. And the Federal program?

Mr. KELSO. I'm going to have Dr. Martin speak to that one.

Dr. MARTIN. The loan repayment program provides that for each year of service in an underserved, isolated area—and predominantly they are in isolated rural areas—we will repay up to $20,000 of their debts, in exchange for 4 years of service, that would be $80,000. That would pretty much cover all the debts that people would have.

The Federal program will probably fully subscribe this year, and in fact there are already 26 contracts signed. We anticipate spending all the money on physicians and nurses serving through the Federal loan repayment program in designated health manpower shortage areas (HMSA). Grants totaling $1 million were made to seven States to carry out the same activity. We are, as Mr. Kelso indicated, concerned about the State's ability to attract individuals to the program.

The underlying premise of this budget regarding the loan repayment program is that the States can and should, over time, assume responsibility for attracting individuals to underserved areas within the State. The current budget proposal assumes that there will be a gradual phaseout of the Federal responsibility concurred with an assumption by the States of that responsibility.

Senator HARKIN. How many health professionals will be employed this year in return for repayment of their loans? Do you know?

Dr. MARTIN. For the Federal program in 1989, we anticipate about 90. Additionally, there is a parallel program we participate with which provides over 150 health professionals to the Indian Health Service. The State program was targeted for 130 health professionals and we are not sure——

Senator HARKIN. And that is the one that has zero placements. Right?

Dr. MARTIN. Yes; to date. We anticipate there will be some.

Senator HARKIN. If we are shifting this to the States—and you say that is what the administration wants to do is to shift to the States, but it doesn't look like the States have the wherewithal to really do it.

Mr. KELSO. Well, the grants we made, the seven, were made in the latter part of 1988, which would make it last fall. So, I think there is a possibility the jury is still out on this, but the fact remains as of right now, they have not made a commitment. Now, that doesn't mean they might in the future.

Dr. MARTIN. I think it is important to emphasize that even with our Federal rural health program activities, we still must utilize the abilities of States, particularly with regard to Medicaid and title XX, to cooperatively work with the Federal Government to resolve rural health problems. Without States actively participating,

we are not going to solve the problems. There are many States that are doing a great deal more with very active offices of rural health which are playing a critical role in resolving rural America's health problems.

Senator HARKIN. Does this budget request represent your initial request to OMB?

Mr. KELSO. No, sir; it does not.

Senator HARKIN. Was it OMB's budget that moved this all to the States?

Dr. MARTIN. The current policy of the administration, both at OMB and the Department, is that this particular function should be a State function. This has been a 7-year policy both at the senior level in the Department and at OMB. It is not just OMB. The fact is our Department has felt very strongly for the last 7 or 8 years that many of these programs can and should be carried out by States.

NATIONAL HEALTH SERVICE CORPS

Senator HARKIN. The National Health Service Corps field program funds have been cut in half.

Mr. KELSO. Yes, sir.

Senator HARKIN. Again, I assume that does not represent your initial request to OMB?

Mr. KELSO. No, sir.

Senator HARKIN. Just this weekend in Waterloo I was informed by the local community health center that they are losing two National Health Service Corps individuals in May, and they have no replacements.

Mr. KELSO. Yes, sir; that is a real problem.

Senator HARKIN. Is this a direct result of this?

Mr. KELSO. I think Dr. Martin's figures indicate that in 1990 we will be short about 400 physicians.

Dr. MARTIN. In 1990, just for community health centers, we will be short about 400 physicians. Previously, we truly felt that with competitive salaries and the very large number of primary care practitioners becoming available, health centers in underserved communities and rural areas would be able to successfully compete in the market for primary care physicians. And, indeed, our program responses were designed around that premise for the last 3 or 4 years. We stopped awarding scholarships. So, the number of scholarships declined. The number of Federal assignees decreased as the number of physicians increased.

Senator HARKIN. Now, tell me again, Doctor. Why would there be enough doctors to go into these underserved areas?

Dr. MARTIN. There had been a number of studies between 1981 and 1986 during this period of very substantial increase in the numbers of physicians. The aggregate numbers of physicians increased dramatically.

Senator HARKIN. Yes.

Dr. MARTIN. In that period of time, studies began to show that those physicians did, indeed—and this is demonstrated—diffuse into counties and communities which historically could not get physicians. What has apparently been true, however, is that for

counties above 10,000 or 15,000 in size there is this diffusion. There is no question about it. More doctors are going to those communities. However, in urban areas, they are not diffusing into the inner cities, and they are not diffusing into isolated rural communities.

So, this projection that we had made, which was a legitimate projection based on the numbers of doctors, doesn't apply for two communities: Isolated rural communities and inner city and/or urban poor underserved communities. Except for that, physicians are diffusing throughout the entire Nation and moving into communities which historically have not been able to attract doctors.

Senator HARKIN. Well, that sure hasn't been our experience out in Iowa, and I can't think of too many States more rural than Iowa with its many small towns and communities.

I'd like to know the longevity of those doctors. A lot of times you might get a doctor in a small community. They are enticed to come there. They go there, and what do they find? They find they are working 7 days a week. They are on call 24 hours a day. Their compensation is lower than their classmates who went to an urban area who aren't on call 24 hours a day. And they don't have a primary care facility nearby that they can utilize. The primary care facility may be 60 or 70 miles away which takes time for them to drive to see a patient and come back. And after about 1 year of that, they are gone, or in a couple years they are out of there. I would like to know what the longevity is.

That is why I say my experience is that we are having a dickens of a time getting doctors in these small communities for just those various reasons.

Dr. MARTIN. I think Mr. Kelso in his testimony indicated that we have come to that same conclusion with regard to the basic assumptions particularly for those communities.

Senator HARKIN. So, we need incentives. We need the loan repayment program, the scholarship program. What else? The scholarship program doesn't really address that I suppoce, does it?

Mr. KELSO. Yes; it does.

Dr. MARTIN. Well, the scholarship program first is targeted. For the last 3 or 4 years it has been targeted to exceptional financial need students who are predominantly minorities which becomes very, very important for particular populations at risk in inner cities and in certain parts of our country such as the South and Southwest.

But when the scholarship program was much bigger, and we would not want to return to the size it was, significant numbers of physicians, in total 11,000, served. So, large numbers of doctors moved into communities throughout the country. In fact, in Iowa today there are 14 National Health Service Corps assignees currently on duty that had a scholarship obligation, and that is why they went to Iowa.

Senator HARKIN. I see.

Dr. MARTIN. Some proportion of those physicians do stay, which gets to the second part of your question. You simply cannot assign a physician out there to an isolated setting and expect it to work. We know that, and we address the problem with the community and migrant health center programs which provide an infrastructure to assist these assignees.

Mr. KELSO. One of the reasons we went to loan repayment is that the scholarship program had a long leadtime. For example, an individual would take a scholarship as a freshman. Eight years later we direct the individual to someplace. His life has changed. His interests have changed, and, in some cases, we have had problems with assignments. The loan repayment program provides an opportunity to execute a contract more closely to the time for service.

Senator HARKIN. Iowa has 23 certified health manpower shortage areas. My notes tell me we have 20 National Health Service Corps doctors. You said 14.

Dr. MARTIN. Fourteen will stay past June. There are six that are finishing their obligations over the next 3 months.

Senator HARKIN. Two of them are obviously in Waterloo; 8 of these 20 doctors will complete their obligation this year. Another seven will finish in 1990. So, you have 15 out of 20, and no Iowa assignments are planned for 1990 or 1991.

With a 50-percent cut in the National Health Service Corps, how are the rural areas going to be able to get these doctors? What are we going to do? What will you advise me to tell my constituents, Dr. Martin?

Dr. MARTIN. Well, my professional advice, other than the budget you see before you, would be to advise your constituents that you saw the error of our budget proposal and you corrected it. [Laughter.]

Senator HARKIN. There's an honest man. What's your name again? [Laughter.]

Dr. MARTIN. I think this particular part of the budget proposal was based on assumptions that we previously supported but now believe are not correct. And it is not a large amount of money, but you are absolutely correct that the scholarship program is essential to recruit, attract, and direct physicians to the places that you are talking about. Without it, we do not have the mechanism to do it.

Mr. KELSO. I think it is safe to say that no matter how many doctors we have, there are places that they just will not go.

Senator HARKIN. That is absolutely true.

Mr. KELSO. They just won't go, and it seems that they can usually find employment in the big cities somewhere.

Senator HARKIN. What happens is if there are many doctors in one area that are performing appendix removals, the number of appendix removals goes up.

Mr. KELSO. Possibly.

Senator HARKIN. You find room for them. I found that too.

Mr. KELSO. Yes.

Senator HARKIN. That is another issue, but I think you are right.

Quite frankly, I see nothing wrong with—some people say, well, in the rural areas we get doctors right out of medical school. They are still learning. They are just getting their feet wet. What we need are more accomplished doctors. I just don't know how to do that. When you are faced with no doctors at all, you are darned thankful to get those just out of medical school. At least then you have a primary care physician that can diagnose illnesses correctly and recommend care in a professional manner. That doesn't bother me all that much. I just want to make sure we have the National Health Service Corps doctors out there.

NURSING HOMES

Let me ask you about nursing homes. In many of these rural underserved areas, the nurses can take up a lot of the slack and perform a lot of the services that doctors have performed in the past. What is the status of the nursing homes mandated in 1989?

Mr. KELSO. Well, here again, loan repayment hasn't worked for nurses either mainly because nurses have other options and their income isn't as high as physicians. There is a great reluctance on their part to take on an obligation of 1 year for a loan repayment of maybe $6,000 or $7,000. They have other options. Thus, we are finding that loan repayment has not been working very well for nurses.

We have a nursing student loan program which provides loans to students or institutions. This is a revolving fund and that is continuing. This was not part of the reduction in the Bureau of Health Professions.

I think it is fair to say, however, that in rural areas, it's difficult to attract nurses. They usually prefer to work in cities in a more high technology facility. Also, the pay is probably better. I can see where it is a real problem.

Senator HARKIN. Community health centers in my State have performed a great function, a great service to underserved and low-income areas. I am sure that is true in other rural areas such as the South and Southwest as you mentioned. We are going to be paying close attention to see what they are doing in terms of recruitment retention. I understand that there is $20 million?

Mr. KELSO. Yes; $20 million.

COMMUNITY HEALTH CENTERS

Senator HARKIN. And the health centers say they need $94 million?

Mr. KELSO. Correct. The community health center budget stays at approximately the same funding level between 1988 to 1990, but there are additional funded activities not in the CHC line. For example, there is a perinatal program with additional money. There is also additional funding for AIDS and the homeless program. Thus, there are three activities with additional proposed funding that relate to community health centers. We also hope that the center will be able to maximize third-party reimbursements.

Senator HARKIN. The budget requests an increase of $1.5 million to $3.1 million to fund the five existing rural health research centers, two new centers, and the Secretary's Advisory Committee on Rural Health, which I might add is chaired by former Governor Ray of Iowa.

Mr. KELSO. Yes, sir.

RURAL HEALTH

Senator HARKIN. Your budget says these funds will also be used for an information clearinghouse on rural health.

The Budget Reconciliation Act of 1987, which authorized the Office of Rural Health Policy, mandated an information clearinghouse. I understand that has not been implemented yet.

Mr. KELSO. That's correct, Senator. We just didn't have the money in 1989. The 1990 budget proposes an increase of $100,000 for the clearinghouse. If that $100,000 is made available, we hope to have the clearinghouse up and going in 1990, It was just a case of fund availability.

Senator HARKIN. I see.

Mr. KELSO. And we felt we had to put priority on the advisory committee and on research grants.

Senator HARKIN. By law, the Office of Rural Health Policy has oversight on HCFA regulations that affect a significant number of rural hospitals. Is there a specific process by which this office reviews these regulations, and do they comment on them in the Federal Register?

Mr. KELSO. Yes, sir; Mr. Human's office has about 10 employees, one of whom is on detail from the Health Care Financing Administration. We have had great success at staff-to-staff coordination and communication, so that we're involved when the HCFA regulations are being developed. We are informed as to when they are going to be submitted to the Secretary's office, and we receive them prior to that time. We are able to comment on them at that time and then NCFA receives our input.

Senator HARKIN. You feel that the Office of Rural Health Policy is working well?

Mr. KELSO. Yes; we feel that we have our opportunity for input.

Senator HARKIN. That is all I wanted to cover with you today, Mr. Kelso. We have some additional questions in writing for the record.

I will recognize Senator Adams.

DRUG TASK FORCE

Senator ADAMS. Thank you, Mr. Chairman. I apologize for not being able to be here for the earlier questioning. We were on the floor passing the sense of Congress and sense of the Senate resolution on the construction of the prisons.

I am chairman of the Subcommittee on the District of Columbia, which Senator Harkin was last time. I regret that I was not here for the earlier panel. I am going to ask you about your coordination with them because I have talked with Senator Kennedy, and we will be holding a series of hearings that focus directly upon the problem that the chairman so well outlined in his opening statement.

My opening statement to you would be this, and then I have question that I want to ask you. I'll be very quick.

STATEMENT OF SENATOR PETE V. DOMENICI

Senator HARKIN. Mr. Kelso, I am going to have to leave. First, I will ask to insert a statement from Senator Domenici in the record.

[The statement follows:]

STATEMENT OF SENATOR PETE V. DOMENICI

I would ask the Subcommittee's indulgence in allowing me to enter a few remarks in the record about a silent war that many families, physicians, and researchers are

waging that gets far less media attention than the war on drugs, but is just as serious a battle. I am speaking of the war against mental illness.

The Subcommittee is well aware of this Senator's interest in advancing research into the causes and appropriate treatment for serious mental illnesses. Great strides are being made in understanding how the brain works. This research will unlock the mysteries of many mental illnesses, and show us a way to treat those who are unfortunate victims of these nightmarish diseases.

This Subcommittee has been very supportive in past years in providing the National Institute of Mental Health (NIMH) with increased roughly equivalent to the overall increases provided to the National Institutes of Health. I submit that much more needs to be done—we are on the threshold of unraveling the puzzle of mental illnesses in this "Decade of the Brain." The $293.5 million that was appropriated for NIMH for non-AIDS research in fiscal year 1989 is another step forward in our war against mental illness. But as a number of advocates and organizations will testify, $500 million could easily be used for the NIMH research program, approximately $430 million of which would be for non-AIDS research into schizophrenia, depression, and other disorders.

These diseases are not invisible, and the people in this room have come far in removing the stigma long associated with mental illness. However, far too few people realize that schizophrenia is twice as common as Alzheimer's disease, five times more common than multiple sclerosis, six times more common that insulin-dependent diabetes, fifty times more common than cystic fibrosis, and sixty times more common than muscular dystrophy. This disease, and other mental illnesses, deserve a war, and a war now.

Mr. Chairman and Members of the Subcommittee, an unprecedented effort has been mounted by the patients, families, and medical profession that lives with the terrible strain of mental illnesses. That effort is the National Plan for Research on Schizophrenia, a comprehensive, national strategy to identify the causes of, and develop effective treatments for, the most serious mental illness—schizophrenia. Launching this initiative through the National Institute of Mental Health holds the most promise for getting at the causes of many of these illnesses. I am convinced that the time to focus resources on this effort is now—the technology to unlock the mysteries of the brain is clearly advanced, and recent scientific achievements make this effort an exciting frontier for our scientists.

Last year, at my questioning, Dr. Judd, the Director of NIMH, testified that the budget request included only $3.6 million for activities associated with the National Plan for Schizophrenia Research. He also told this Subcommittee that as much as $57.8 million could be used by NIMH to get this "war" underway. I hope the Subcommittee will again ask Dr. Judd how much the fiscal year 1990 budget request focuses on the National Plan and how much NIMH could use. I fully support this exciting research effort and hope the Subcommittee will join the efforts of so many to wage this silent war.

Senator HARKIN. Senator Cochran also has some questions for the record which we will submit for the record.

Again, thank you for being here.

Mr. KELSO. Thank you very much.

Senator HARKIN. I will turn it over to Senator Adams.

Senator ADAMS [presiding]. The fundamental question I will give you first, and then I will ask you how you are coordinating with it.

We had in our original panels that testified on what we were going to do to meet the enormous homicide rate and the crack epidemic, first in the District of Columbia, but really throughout the entire country. The President has made it a key program. The drug czar has testified about it.

We invited in two specialists to give us just an opening statement on it. They indicated that with regard to crack—and we called them particularly because the chief of police and the mayor said that this had appeared in Washington, DC, about 18 months to 2 years ago, and that it has appeared elsewhere in the country a little earlier. In other areas, and I have checked in my home city, which is Seattle, that the cases have gone from 82 to over 182 in less than 6 months.

We are spending a great deal of time and effort at the moment, and what we were doing this morning, as I started to say to you, was to pass the necessary resolutions to have additional prisoner holding space available. We are attempting to put an additional number of police on the streets, and so on. But all of this is directed toward stopping the killing and trying to prevent the homicides, stop the bleeding so we can get at the problem.

Now we want to talk with you about the problem. The hearings that we will be setting up—and I know that you all talk with one another—will be to determine what the National Institutes of Health and the other particular groups—where you are on your research, what you can say to us about this new plague. We understand from the testimony we received that there are no inhibiting drugs like methadone for heroin in this case.

And so, Doctor or whichever one of you would like to comment—and I'm sorry that Dr. Goodwin was already there. I have the question: Do we have a coordinated program that you are involved in with the others? Is it funded sufficiently? And where are we with the potential treatment for at least stabilization of crack addicts?

It is of enormous urgency to me because we have a rotating, swinging door here at the moment with people going back out on the streets with an enormous amount of violence. We had more people killed here last night than have ever been killed in Washington, DC, since the Hanafi murders. We have had more homicides or more people killed on the streets of Washington, DC, to this date than were killed in Beirut this year.

So, we are not talking about something that we can ignore. We are trying to handle the police problem, but now I would like to have you talk to me about the medical problem.

I will be calling hearings because I am on the Labor and Human Resources authorizing committee as well as this subcommittee on appropriations. But I wanted to start with you on that.

Mr. KELSO. The agency we represent, the Health Resources and Services Administration, has a grant in the District of Columbia in three different locations.

But, fortunately, to my right is Dr. Martin who was asked by the Assistant Secretary for Health Designate to chair an illicit drug task force. So, in that extracurricular hat, I think he might want to respond to you.

Dr. MARTIN. Given Dr. Bennett and the President's efforts to begin to consolidate both the—or to create a Federal consolidation of efforts on the supply and demand side, I would have to say that most of the current publicity predictably is going to be directed at the hemorrhage and the symptoms of the basic activity. And that is where Secretary Kemp, Dr. Bennett, and others—and that has been most of the coverage.

It is fair to say that on the demand reduction side, Secretary Sullivan has been very clear about the priority within the Department. Members of his staff and the other agencies have been working to determine not only what our Department can do, but what we can do in conjunction with other domestic departments. Specifically around the medical or public aspects of this particular problem, Dr. Mason who, as you are aware, is the Assistant Secretary Designate for——

Senator ADAMS. I talked to him this morning.

Dr. MARTIN. He has requested that each agency administrator in the Public Health Service personally participate in working together to come up with a proposal to submit to the Secretary to develop an interagency activity associated with the epidemiology of not only crack, but if you are from the State of Washington, the new meth-amphetamines are probably in your rural areas going to be as much or more of a problem in a decade.

Senator ADAMS. Repeat that for me?

Dr. MARTIN. Meth, m-e-t-h. The new specialized drugs that are beginning to really impact in rural America that can be made basically local.

So, it is not just simply a question of a drug. It's what the epidemiology of drugs, what is the impact on which parts of our community, and what can we predict.

Second, he was very concerned about NIH, ADAMHA, CDC, and FDA looking at the current research efforts. How can we augment, expand our activities? How can the Food and Drug Administration work more effectively with ADAMHA around suppressor drugs and/or inhibitor drugs?

On the regulatory side, there is a set of very important kinds of issues associated with other drugs which are a part of the substance abuse problem.

Finally, on the treatment and services sides, which very specifically is going to be an issue in the District of Columbia, there has already been money appropriated under the Omnibus Drug Act to expand the number of treatment slots. There have already been fundamental changes in the regulations associated for methadone proposed by ADAMHA and FDA.

I think, Senator, that you can anticipate that over the next 3 or 4 weeks the plan that Dr. Sullivan will be working with Dr. Bennett on will incorporate a fairly visible and aggressive cooperative effort on the part of the whole PHS. As you know, Dr. Goodwin, who has the clear lead for drug abuse activities within the Public Health Service testified before, but he is very actively working with other agencies and Dr. Mason to assure that we have a comprehensive plan.

Senator ADAMS. Within the homeless population, are you collecting data regarding cocaine and crack addiction in this population?

Dr. MARTIN. We are collecting specifically at the Federal level information on what proportion of the homeless patients are being provided counseling and/or referral and follow-up for substance abuse. We make the distinction between IV drug use and non-IV drug use. Obviously, at the center level, it is possible to make that judgment locally.

One of the very serious concerns that I think that we need collectively to have in public health is the scientific integrity of information we are collecting on who are the drug users, what types of drugs, what is the severity of the particular addiction, what are the other types of codependencies associated with their families and their living environment. Very frankly, although we have very good data in the survey that NIDA does, that type of community epidemiology information probably is one of the first priorities to

be dramatically increased so we know much better what is going on.

Senator ADAMS. Do you have any estimates on crack usage among pregnant homeless women?

Dr. MARTIN. We can provide that.

Senator ADAMS. Now, have your National Health Service Corps doctors encountered crack in the rural populations? We are trying to get some idea, as we start to focus on these urban areas, that we are not ignoring the rural areas. But I believe you said to me that we probably have out there more the meth-amphetamines and so on.

Dr. MARTIN. I think it is fair to say that all substance abuse problems to degrees are being found throughout the country. I think what you find is terrific variability in particularly communities and/or States and/or regions or areas.

I would have to say for crack, as an example, there is almost by definition no part of the United States that is immune from the sale or distribution of crack. I think the character of the problem is dramatically different in most rural areas and in, frankly, most urban areas than it is in some of the very visible cities where crack has become epidemic, the District of Columbia being, of course, the classic example of that.

But that information we can submit to you for the record, Senator, from ADAMHA.

Senator ADAMS. Would you please submit it to the committee for the record?

Dr. MARTIN. Yes, sir.

[The information follows:]

CRACK USE BY HOMELESS PREGNANT WOMEN

Currently the National Institute on Drug Abuse [NIDA] has no data on the number of homeless pregnant women using crack form of cocaine. However, recently NIDA has funded a number of research grants, where the investigators are studying a number of aspects of drug abuse among pregnant women and its obstetric and neonatal consequences.

Even though no estimates are available on homeless pregnant women, some data on the pregnant women using/abusing illicit drugs are available. Preliminary data from a recent pilot survey of 36 hospitals in the U.S. (conducted by one of NIDA's grantees, Dr. Chasnoff, Chicago), show that of about 155,000 women who delivered at these hospitals, about 11 percent had used one or more illicit drugs (heroin, methadone, cocaine, amphetamine, phencyclidine [PCP], and marijuana) during pregnancy. The author concluded that drug use among the pregnant women in the study was underreported. In fact, 15.7 percent showed positive in a sub sample of 15 hospitals when subjected to urine toxicology screening. Further indepth analysis of data available from 9 hospitals showed that among the 8,858 pregnant women, the incidence of cocaine use/abuse was about 15 percent. No distinction was made between cocaine and crack cocaine.

Thus, no estimates of the exact number of pregnant women using/abusing cocaine can be made at this time. A number of additional studies are in progress which will provide incidence/prevalence of cocaine and other drugs used during pregnancy and thus the number of babies born to drug using mothers.

Senator ADAMS. I certainly didn't want and don't want any of you to feel that because of my questions this morning that I am interested only in the drug problem. I have a very deep interest in our rural health problems which are severe in our State for the reasons that Chairman Harkin was mentioning before. We just simply cannot keep our young doctors in the small communities.

We have an interest also in trying to—and you might answer this in writing to the committee as to whether or not it is possible for us to take some of the health clinics that we have in our rural and particularly our agricultural communities and in some fashion place them into a Federal status where they are connected with the Federal Tort Reform and Tort Act. I am a former U.S. attorney and I have handled those cases. Our problem is getting malpractice insurance. If you can come up with a creative idea as to how they can be blanketed into the Federal system, we maybe can get some of them to start delivering babies again in some of these places.

[The information follows:]

MEDICAL MALPRACTICE INSURANCE IN UNDERSERVED RURAL AREAS

Protection from malpractice liability is provided by the Federal Tort Claims Act for Federal employees and applies to any physician practicing at an NHSC site who is also a Federal employee.

In order to take advantage of the coverage available under this statute, it is proposed that a legislative amendment to the Tort Act be made that would also allow coverage for a select group of physicians who are also members of Public Health Service [PHS] Inactive Reserve practicing at community and migrant health centers and designated free standing National Health Service Corps sites.

Upon enactment of this proposed legislative change, the PHS could then screen individuals for inclusion on the list of physicians who would be provided malpractice coverage under the Federal Tort Act. This screening would utilize the PHS inactive reserve officer commissioning process to ensure that professional credentials and competency are acceptable to the Federal Government.

Mr. KELSO. We'll be glad to put something in the record.

Senator ADAMS. We would appreciate whatever suggestions you may have because we will on both the authorizing committee, as well as here, attempt to deal with that problem because that is a severe problem for us not only just obtaining the personnel, but where we have them, being able to keep them or being able to allow them to function.

Are there any other comments that any members of the panel wish to make?

[No response.]

Senator ADAMS. If not, I appreciate your being here, and so does Chairman Harkin. I apologize that I couldn't be here earlier. I expect to be here at all of these. I am very interested in them. It's just that this morning became a very difficult morning.

Mr. KELSO. Thank you very much.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator ADAMS. I have other questions and perhaps some of the other members do, too, that we will submit.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HEALTH PROFESSIONS EDUCATION

Question. We hear a lot about the "doctor glut." If a glut exists, it hasn't helped small rural communities. They average just 53 doctors to every 10,000 people, while the national average is 163 doctors to every 10,000 people. Today, there are 34 million Americans living in designated health manpower shortage areas, where there is just one doctor to every 3500 people. According to HRSA's calculations, it would take 4500 primary care doctors in those areas to remove the "underserved" designation.

Yet the Administration has proposed eliminating just about every dime of assistance to individuals and institutions for training in health care, including for areas suffering critical shortages of primary care doctors, nurses, and others.

How do you justify eliminating health professions education funds when there are critical shortages?

Answer. To date the Federal Government has spent $5.1 billion for these programs since 1965. In view of the fact that the aggregate shortage of health professionals has abated, and the targeting of Federal resources to other priorities, such as AIDS, biomedical research, and alcohol and substance abuse, the Administration proposes not to fund health professions education programs. Compared to such concerns as AIDS, these training programs are less pressing and are more amendable to alternative sources of funding support.

Question. And how do you justify cutting the National Health Service Corps field program funds in half when it is the only program we have to get help to underserved areas?

Answer. As Dr. Martin explained previously, the budget before you is based on the assumption that the growing supply of doctors would cause diffusion to the areas to which we have traditionally assigned National Health Service Corps staff.

Question. Are we training enough primary care doctors, nurses, geriatric specialists, and allied health professionals to meet current and future needs as projected by HRSA and the Council on Graduate Medical Education?

Answer. The question as to whether or not an adequate supply of health professionals and allied health personnel are being trained to meet the future needs of this Nation is a multifaceted one, which cannot be answered easily. The supply of health personnel is increasing in the aggregate and for specific professions, and will, in the aggregate, increase at a fast enough rate to keep pace with the demand for health services. The Sixth Report to Congress (June 1988) addressed this issue specifically, with separate discussions on each of the occupations and the factors affecting them. Overall it appears that the supply of most occupations will be adequate to meet the Nation's needs through the end of this century.

Despite a recent drop in the number of persons applying for and enrolling in many health professions schools, the number of health care personnel continues to increase. Although the health professions have grown at varying rates, all have continued to exceed the growth rate of the U.S. population. During the period from 1980 through 1986, increases in the number of physicians, dentists, podiatrists, pharmacists, optometrists, veterinarians and registered nurses have ranged from about 11 to 33 percent, and have averaged about 21 percent for the large and diverse group of allied health occupations. The growth in the U.S. population during this period, was about 6 percent, demonstrating that the supply of health professionals has exceeded the U.S. population growth.

During the 1980-1986 period, the number of primary care physicians has grown at a faster rate than other physicians; they make up about two-fifths of all physicians, or nearly one-half of all patient-care physicians (AMA). As the aggregate physician supply is expected to exceed overall requirements for the foreseeable future, we do not expect a shortage of primary care physicians (although some areas may remain underserved due to physicians' location decisions). On the other hand, we don't expect the numbers of general practitioners and family practitioners to adequately meet the demand for these physicians. For example, the First Report of the Council on Graduate Medical Education (COGME) concluded that "Maldistribution remains a serious and complex problem, requiring solutions more broadly based than those focusing exclusively on medical education."

Geriatrics and gerontology programs have been constrained in their training of geriatric specialists by a shortage of faculty specially trained to teach about health care for the aging (Report, Executive Summary, page 4). The COGME concluded that "Additional emphasis is warranted in the general areas of geriatrics and preventive medicine."

NATIONAL HEALTH SERVICE CORPS (NHSC)

Question. Iowa has 23 certified Health Manpower Shortage Areas, and 20 National Health Service Corps doctors. Eight of these doctors will complete their obligation this year, and another seven will finish in 1990. No Iowa assignments are planned for 1990 or 1991.

With a 50 percent cut in the National Health Service Corps, how will the rural areas of my state be able to recruit doctors? What is the Department doing to help health manpower shortage areas fill the gap left by the decline of the National Health Service Corps?

Answer. The National Health Service Corps has recently initiated a national recruitment effort and operates a national recruitment and referral service as a part of that overall effort. In addition, the States will be assisted by the availability of the Federally funded State operated loan repayment program. These efforts will provide States with some assistance in staffing underserved areas. Despite these efforts, our experience to date indicates that the loss of supply resulting from the termination of the NHSC scholarship program will be very difficult to fill.

Question. What is the status of the nursing loans mandated by Congress in FY 1989? How many loans have been made, and what funds have been expended so far?

Answer. The NHSC initiated an aggressive nurse recruitment effort last year. We offered loan repayment as an added benefit to attract nurse practitioner/midwives for the most difficult to staff areas.

To date we received indications of interest from 20 nurse practitioners/midwives for whom loan repayment may be helpful. These individuals are generally from high priced programs (Yale is an example) who come out of training with debts in excess of $20,000 to $30,000, however none have signed up so far. Nurses as a rule do not seek or qualify for loans in nursing school or training programs. The expected salary levels after graduation are not sufficient to pay back loans nor is the repayment of the debt load usually sufficient incentive for the commitment we are requiring.

STATE LOAN REPAYMENT

Question. The budget proposes no funds for National Health Service Corps scholarships, and proposes shifting all funds for the loan repayment program to the states. This is very disturbing: I understand that the state loan repayment program hasn't placed a single doctor yet.

Without a federal scholarship or loan repayment program, would there be any tool for recruiting doctors to shortage areas?

Answer. The programs you mention are the programs that we have traditionally relied upon to supply health professionals to shortage areas. As we have been discussing, these programs have been proposed for phaseout or elimination based on the assumption that the growing supply of doctors would cause diffusion to the areas for which we have been using the NHSC programs to recruit.

Question. How many health professionals will be employed this year in return for repayment of their loans? How many do you expect to place in 1990?

Answer. Due to start-up delays the States have not entered into any firm contracts under the FY 1988 grant awards. Because of the difficulties the States appear to be having in obtaining commitments this year, and until we see what success the States have with the program, we cannot provide any reliable estimates for FY 1989 or FY 1990.

Question. Under the proposed state loan repayment program, what is a realistic estimate of how many doctors could be placed in 1990?

Answer. Due to start-up delays we have not yet been able to evaluate the program in order to determine the States ability to attract practitioners.

Community and Migrant Health Centers, especially in rural areas, are dependent on the National Health Services Corps for their medical staff. The State loan repayment program has yet to bear fruit as an effective method of placing doctors in shortage areas.

Question. If the loan repayment program in FY 1990 places no more doctors into the program than in this year, what will be the net effect on Community and Migrant Health Centers? How many communities could be left without services?

Answer. Based on our best projections in fiscal year 1990 there will be a shortfall of approximately 450 physicians to meet the needs created by 800,000 existing and new users of centers. Some smaller centers, which could lose all their physicians, would as a result have to cease operations; however in most centers the impact of the shortfall of physicians would be an increase in waiting times and a discontinuation of some type of services.

Question. What are you doing to help health centers recruit doctors?

Answer. In 1989 we are awarding approximately $20 million in an effort to recruit and retain physicians at CHCs and MHCs. The funds will support salary and benefit increases and professional support activities. In addition, we believe that in order to attract sufficient numbers of physicians to serve at CHCs we must adopt a multifaceted approach including the following:

1. A good working environment must be maintained at centers. This refers to physical working conditions, equipment, staff support, and management practices.

2. Salaries must be increased to be more competitive with other practice options such as hospital and HMO employment, and private practice. In 1989, the centers are receiving over $20 million to increase salaries and benefits in an attempt to retain physicians. Although the centers will never be able to pay salaries equal to what competing employers can offer, it is essential to have salaries as competitive as is feasible.

3. CHC practitioners must be able to obtain hospital privileges in or near the area where the center is located. This is important for professional development and satisfaction, and to enhance the esteem of center practitioners within the community.

4. CHC's must develop and maintain good relationships with other medical practitioners in the community again for reasons of professional esteem and personal satisfaction and because these relationships are of benefit to the center.

5. States must become more aggressive and innovative in recruiting by offering inducements for physicians to come

to the center such as signing bonuses, loan repayment programs, scholarships, and other means of persuading a physician to make a commitment to practice at a CHC.

Question. How much did the health centers say they needed for recruitment and retention?

Answer. As I mentioned, in FY 1989, the PHS will award approximately $20 million in supplemental grants to Community/Migrant Health Centers for costs associated with the retention and recruitment of physicians. These dollars compare with $92 million requested by the grantees and $35 million recommended for the funding by independent PHS Review Committees.

Question. Of the $20 million used in FY 89 for recruitment and retention, how much was used to recruit allied health professionals?

Answer. The focus of the funding is to retain and recruit physicians, however $100,000 of the amount awarded is being used for recruitment and retention of mid-level practitioners.

RURAL COMMUNITY HEALTH CENTERS

Question. Rural community health centers are being crushed by economic decline of rural America. According to the National Association of Community Health Centers and the National Rural Health Association, between 1986 and 1987, their operating expenses rose 14 percent due to increased demand for services, their expenses to subsidize poor patients rose 11 percent, and bad debt increased 25 percent. Yet federal grants rose by only 11 percent, not enough to cover the shortfall. Furthermore, it appears that the lion's share of the funds we provide for additional grants to centers for infant mortality, homeless, and AIDS go to urban centers.

What are you doing to help the rural centers? How can they weather this storm?

Answer. The budget requests an increase from $1.5 million in FY 1989 to $3.1 million in FY 1990 to fund the five existing rural health research centers, two new centers, and the Secretary's Advisory Committee on rural health, which is chaired by former Governor Robert D. Ray of Iowa. The budget will be used for an information clearinghouse on rural health.

Question. The Budget Reconciliation Act of 1987, which authorized the Office of Rural Health Policy, mandated an information clearinghouse. Why hasn't it been implemented yet? When will the clearinghouse be operational?

Answer. We have requested $100,000 in FY 1990, and expect to have the clearinghouse in place by the end of that fiscal year. What we are building is a clearinghouse, not a library. We will have an index of materials and sources but not a permanent collection. We will be able to refer users to the relevant materials and where to secure them. In most cases we will not be able to provide the materials directly.

Question. How is the work at rural research centers coordinated so that centers are not duplicating each other's work? What areas of research will you be looking to the new centers to conduct?

Answer. We negotiate with the centers and select not only on funding, but on projects. This assures there is no duplication. Then we met with the centers and with a number of other groups that are doing rural research, including the Office of Technology Assessment, the Health Center Financing Administration, the National Center for Health Services Research, and others in our Department. In this joint meeting, we assured a boarder coordination of research efforts. We will be holding such meetings every 6 months. Next month, in fact, we will have the second meeting, that will also include the Robert Wood Johnson Foundation, the General Accounting Office, and the HHS Office of the Inspector General. We are trying to provide leadership in coordinating not only our centers' research, but other important rural research as well.

By law, the Office of Rural Health Policy has oversight on HCFA regulations that affect a significant number of rural hospitals.

Question. What is the specific process by which the office reviews regulations -- does the office comment on proposed regulations before they are published in the Federal Register?

Answer. When the Health Care Financing Administration is ready to publish a proposed regulation, they send it throughout the Department for review. They now use a short-cut to get the notice to the Office of Rural Health Policy directly and quickly when the comment period occurs. The comment period often is very brief. Sometimes the office has only a day to prepare comments. However, since they have a good system of informal communications with the Health Care Financing Administration, they ordinarily have advance notice that a regulation will be coming and roughly what it says.

Once the office has completed its comments, they go through regular channels through the Public Health Service and the Office of the Secretary and back to HCFA. During this process, no one changes the comments of the office. They may disagree with them, but no one changes them.

Question. Is the agreement between HCFA and the Office of Rural Health Policy fulfilling the spirit of the authorizing law?

Answer. We are quite satisfied with the agreement and with the performance of HCFA. Mr. Human and his staff meet regularly with top HCFA staff and they work together to shape general approaches to regulations development, policy, and even some legislative approaches. I believe that this process has resulted in a better break for rural hospitals and providers than they would otherwise have received.

On the more narrow issue of HCFA's response to the comments of the office, I am also pleased. The comments of the office usually are substantive and sometimes recommend quite different approaches. HCFA carefully considers the comments and sometimes makes the changes.

SECRETARY'S ADVISORY COMMITTEE ON RURAL HEALTH CARE

Question. I understand the Secretary's Advisory Committee on Rural Health Care has been meeting and is working on a number of recommendations on rural hospitals and health personnel.

When will the recommendations of the Advisory Committee be available to Congress? How do you plan to implement the Advisory Committee's recommendations?

Answer. The very first project of the office in 1987 was to work with the Secretary to convene a National Advisory Committee on Rural Health so that he could have the best advice from people who best understand these problems. That committee was established in the spring of 1988. Former Governor Robert Ray of Iowa was selected as its first chairman.

The committee had an organizational meeting in September of 1988. At that meeting they established as their first priority the achievement of "equity" in Medicare reimbursement for rural hospitals. They also received the advice of several members of Congress including Senators Durenberger and Baucus.

In January of this year, the committee held its second meeting in Jackson, Mississippi. They broadened their first priority to include equity in Medicare reimbursement for rural physicians. They broke into work groups on health finance, health services, and health professions. They agreed to try to develop recommendations on rural hospitals reimbursement at the May meeting. Governor Ray Mabus and other State officials presented advice to the committee.

Work groups of the committee have been meeting this spring, in person and through conference calls. This is a very hardworking group of volunteers.

We expect the National Advisory Committee on Rural Health to begin making substantive recommendation at their May meeting. They are close to recommendations on changes in Medicare reimbursement to rural hospitals. Other recommendations on health services and health professional shortages also may be forthcoming but they are more likely at the September meeting. As soon as these recommendations are sent to the Secretary, they become public and available to Congress upon request.

It is too early to predict what committed recommendations we will want to or be able to implement. Remember, they have not yet formulated any specific recommendations on health care. The Secretary may disagree with some recommendations. Some recommendations may require legislation or appropriations. All I can promise is that we will see that these recommendations get to the Secretary and we will work to get a clear response to each of them from him.

RURAL PHYSICIAN-HOSPITAL LINKAGES ARE NECESSARY

Question. HCFA issued proposed regulations in January that would prohibit hospitals from buying or partially funding physician practices in order to create a pipeline for patient referrals.

I think it's fair to constrain anti-competitive relationships in competitive markets, but this just isn't the case in many rural communities. In these areas, the best way to keep hospitals and doctors serving the community is to encourage these linkages. If a rural hospital helps a physician with rent, malpractice premiums, or other expenses, it stabilizes the practice. And the patient referrals stabilize the hospital. For rural areas, the important point is not competition, but continuity of care.

In your opinion, if the regulations are not changed to reflect the different nature of rural health care, will that compromise access to care?

Answer. Mr. Chairman, we share your concern and when the regulation was first published, we wrote to the Office of the Inspector General on this issue. We strongly recommended to the IG that rural hospitals should not be barred from purchasing a physician's practice when it can be shown that such a purchase would help to preserve access to health care for Medicare and Medicaid beneficiaries in the community. It has not been uncommon for rural hospitals to buy the practice of a physician who is not making a living in the community and then compensate him or her in some way to retain that physician in the community. We agree with you that competition is not always the issue in such cases. The real issue is preserving access to care.

Question. How will the Office of Rural Health Policy assure that these regulations do not outlaw relationships between rural hospitals and doctors that promote quality and efficient service?

Answer. The Office of Rural Health Policy has no authority to enforce these regulations as they affect rural hospitals. That responsibility has been given to the OIG in the Department.

DEFAULTED HEALTH EDUCATION ASSISTANCE LOANS (HEAL)

Question. As of September 30th, over $85 million worth of HEAL loans had been made. Of that amount, $4 million had been written off due to borrowers' death or disability. The rest, over $80 million, is in collection status. This includes $27 million to be referred to a collection agency and $24 million to be referred to the Department of Justice for litigation.

The Department was talking about a $30 million reprogramming to cover defaults on HEAL loans, but we haven't seen it yet.

Are we going to get a reprogramming request?

Answer. No. On March 22, the reprogramming request was withdrawn due to the SLIF balance remaining positive in FY 1989.

Question. What will the impact of this request be on the health professions education grant programs such as family medicine and general dentistry? Most of the residency programs start in July, and I understand they can't get funds until this request is officially withdrawn.

Answer. There will be no impact on the health professions education grant programs. Concurrent with the withdrawal of the reprogramming proposal, I instructed the Bureau of Health Professions to take appropriate steps to obligate all of its FY 1989 appropriation, including the $29,880,000, on qualified and worthwhile projects.

Question. What is the status of the $27 million worth of claims to be referred to a collection agency?

Answer. The $27 million worth of claims reported as of 9/30/88, have been referred to the collection agency. The collection agency will have 6 months to bring the account into a paying status. If the account is not in a paying status within the 6 months, the account is prepared for referral to the Department of Justice (DOJ).

Question. What is the status of the $24 million worth of claims to be referred to the Department of Justice for litigation? Have any claims resulted in litigation?

Answer. We have referred $12 million of the $24 million in claims to the DOJ. The other $12 million in claims are being prepared to be referred to DOJ.

In addition to the above we collected $77,263 in offsets for tax year 1987, and to date, we have collected $73,815 in offsets for tax year 1988. Also, we have met with personnel from HCFA to initiate the Medicare Offset program.

NURSING SHORTAGE

Question. In its report issued last December, the Secretary's Commission on Nursing highlighted the terrible problems caused by the current nursing shortage, and noted that the shortage is exacerbated in rural areas.

What role will the Department play in responding to the current nurse shortage?

Answer. While the Federal government has a limited ability to directly address the major problems identified by the Commission, the Department will continue to take steps to provide leadership in the resolution of these issues. The Commission's report will assist the Administration in developing its health agenda. Some steps have already begun, for example, we have asked HCFA to examine the effect of Medicare reimbursements on nursing compensation, and whether there has been a significant impact on nursing retention.

The HHS Policy council reviewed the Commission's recommendations and directed that the PHS should initiate implementation of the recommendations within existing/planned resources. The PHS is also to promote private sector

implementation. PHS will continue efforts of working with the States, the health care industry, and other private sector organizations, to enhance and increase their support for nurse training.

Question. Which of the recommendations of the Secretary's Commission on Nursing will the Department be implementing immediately?

Answer. The Assistant Secretary of Health recently requested that HRSA assume lead responsibility within the PHS for assessing the Final Report of the Secretary's Commission on Nursing. We have been requested to develop PHS Implementation Plan by April 21, 1989. This action is consistent with decisions reached at the January 18, 1989 meeting of the Department's Policy Council. HRSA will undertake the assignment using the resources of the Bureau of Health Professions with the assistance of the Chief Nurse Office.

Question. What are some examples of successful efforts of rural health care facilities to attract and retain nurses?

Answer. I have to start by noting that, in general, rural hospitals are less successful at competing for nurses and other health professionals than urban hospitals. The urban facilities have more resources and are able to offer higher pay, better fringe benefits, and better access to advanced training.

So, the examples I present are more the exceptions than the rule. Onaga Community Hospital, a 20-bed facility in Onaga, Kansas pays $3/hour night bonus. Each shift is staffed with 2 RNs, thus providing peer support and consultation; 24-hour supervisory call is also available. To enhance the knowledge and skills of its nurses, the hospital offers a strong orientation program, provides planned preceptorships at a larger urban facility in specialty areas, provides tuition reimbursement for nurses who wish to further their education and for employees who enter nursing programs, and is developing a rural nursing continuing education program. The hospital also sponsors a day care center for children of hospital employees. Currently, they have no vacancies and a waiting list.

North Lincoln Hospital, a 49-bed hospital in Lincoln City, Oregon offers a "flexible" 12-hour shift which includes a 10 percent differential for days and a 17 percent differential for nights. Flexibility is provided by allowing individuals to split 12-hour shifts. The community plays an active role in recruiting and retention by financially supporting continuing education for critical care nurses. The hospital auxiliary also provides an annual award for a nurse to return for additional education. The hospital's unit-based quality assurance program is based on a strong collaborative effort between physicians and nurses and advice and support from Board members. Day care is available for children of hospital employees. North Lincoln also has filled all of its current vacancies.

At both hospitals the administrators provide a supportive and creative environment for nursing.

Other successful models of recruiting and retaining nurses in rural health settings include those that involve collaborative arrangements with nursing educational programs. The rural family nurse practitioner training program at Georgia Southern College recruits nurses from rural areas for its program and provides clinical training in rural facilities. Seventy-nine percent of the program's graduates have returned to rural areas where they work with underserved populations.

A second educational/service model is that of the Nursing Center associated with the University of Wyoming School of Nursing. Nursing care and health education are provided to rural individuals by nursing faculty and students in an outpatient facility. This agency's Division of Nursing has provided grant support to both these educational programs.

HOMELESS

Question. As part of President Bush's commitment to fully fund the McKinney Homeless Assistance Act, you have proposed to increase the FY 1990 budget request for health services for the homeless by $49 million. This is a substantial increase over the initial request of $14.8 million.

Do you plan any changes in the method of distributing these funds?

Answer. The major difference is that in 1990 the awarding of grants will be on a competitive basis. The 109 grantees that are currently operating were funded for a two year project period and thus did not compete in FY 1989 but were in a continuation year. In 1990, these grantees must compete for funding with other applicants. It is expected that approximately 150 awards to metropolitan and rural areas will be made.

Question. How many homeless people have been served by this program, and how many more do you expect to serve if the budget request is approved?

Answer. The 109 existing grantees reported serving approximately 230,000 homeless individuals in 1988 and project that they will serve approximately 400,000 in 1989. At the level of the 1990 request, it is anticipated that about 600,000 homeless individuals will be served.

Question. How many grantees do you currently have in rural areas, and how many grantees do you plan to fund to serve rural homeless?

Answer. Nineteen of the 109 existing Health Care for the Homeless grantees are rural or have rural components. As I mentioned, the 1990 funds will be distributed on a competitively awarded basis and we do not know how many grantees will be serving rural populations at this time.

Question. What evaluations have you conducted of services to the homeless? How effective have our efforts been?

Answer. Preliminary data on the 109 projects recently compiled from grantee progress reports indicate that the projects have been successful in bringing health care to homeless people in their communities. The projects exceeded their projected goals during their first year of operation despite start-up delays.

HANSEN'S DISEASE CENTER

Question. What are the Department's plans for the Gillis Long Hansen's Disease Center? Are you pursuing a plan to contract out treatment for Hansen's Disease patients while moving the research to a site other than Carville?

Answer. A study has been completed and is under review. When approved it will be forwarded to the committee. Relocating the research facilities and contracting our treatment services at Carville are among the options under review.

ADAMHA-HRSA SERVICE AGREEMENTS

Question. Please provide the Subcommittee with a list of services that HRSA conducts under reimbursable agreements with ADAMHA.

Answer. We currently have two agreements with ADAMHA:

1. National Institute of Drug Abuse, to enable the Bureau of Health Care Delivery Assistance within HRSA to award demonstration grants to community based health care organizations to expand drug abuse treatment.

2. National Institute of Mental Health, ADAMHA, to provide partial funding, with MCH, of a grant to the Georgetown University Child Development Center in the area of Severely Emotionally Disturbed Children and Adolescents.

HEAL LOANS

Question. What do you anticipate the SLIF fund balance will be at the end of FY 1989, and for the four quarters of FY 1990? Please specify the assumptions used to make this determination.

This year, the budget authority for the HEAL loan guarantees totals $230 million, and 23,000 students of health programs are borrowing an average of $10,000 each. That all adds up.

For FY 1990, The Administration also wants to limit borrowing authority to $100 million based on a projection of 10,000 borrowers. At the same time, your budget proposes to eliminate all funding for health professions education programs. That makes me think students are more likely to need loans, not less likely. Your proposal doesn't add up.

Answer. In view of the continuing changing dimensions of this program, including uncertainties resulting from the litigation process, and although the trend towards a negative SLIF balance is clear, the timing of its occurrence by specific month or quarter is an extremely difficult event to predict with any certainty. Recent

analysis of income to the SLIF and claims paid from the SLIF indicate that the account could become insolvent as early as August of this year, and that the deficit will continue to increase during the next 4 or 5 years.

Given the current SLIF status and the claims experience expected the Bureau of Health Professions estimates that the shortfall in this account will be approximately $150 million to $200 million over the next 3 or 4 years.

Question. Can you explain how you came up with a total of 10,000 borrowers, down from 23,000 this year? How did you determine that $100 million in loan guarantees would be sufficient to meet the needs all students?

Answer. The total HEAL liability at the end of 1988 was approximately $2 billion. In order to limit future liability the Administration proposed that only $100 million in HEAL loans be insured in FY 1990.

At an average cost of $10,000, the $100 million would fund 10,000 borrowers. Health Professions Students unable to obtain HEAL loans should be able to obtain funds from the Department of Education's Guaranteed Student Loan Program, and other loan and scholarship resources available through State and local government programs and private endowments.

Also, the Department's health professions and nursing revolving loan funds will make loans totaling approximately $86 million to about 32,500 students.

There have been a lot of changes in the HEAL program in the past couple of years, both regulatory and legislative. I understand a study is underway to design a model for forecasting the income and expenses of the SLIF fund.

Question. When can the Committee expect an initial report on the study and development of the model?

Answer. In March, 1989 a contract was awarded to the Development Assistance Corporation (DAC) to design a financial model of the HEAL program which can be used to forecast income and expenses of the SLIF. Following discussions with HRSA staff and representatives from the Association of American Medical Colleges and the American Association of Dental Schools, and an examination of recent regulatory and legislative changes in the HEAL program, the contractor is in the process of defining the variables to be used in the model and the structure of the model. In addition, other approaches to projecting income and expenses of the SLIF are being investigated. A mathematical regression model is being developed which, when completed, should provide more accurate determinations of when loans will enter repayment. Also, we are developing a system whereby our short-term estimates of the SLIF balance will be updated monthly to incorporate monthly changes in income, claims and amounts in litigation. This will provide an increased ability to determine SLIF cash shortfalls.

The Administration has proposed increasing the insurance premium on HEAL loans from 8 percent to 14.6 percent. If we accept the Administration's proposals to eliminate federal support for institutions and students in the health professions, HEAL loans would become the only option for many students.

Question. At current rates, can you estimate the impact of the Administration's proposals on current and future HEAL borrowers?

Answer. Should the HEAL insurance premium be increased to 14.6 percent some borrowers who can obtain less expensive funds will do so. Others will continue to borrow HEAL funds. We are unable to estimate the exact impact of increasing the insurance premium.

Question. What is the status of the proposal to sell defaulted HEAL loans?

Answer. HRSA has reviewed OMB and Department of Treasury guidelines concerning the sale of rehabilitated loans. As a result, a small purchase order is being developed to secure the services of a financial advisor for the purpose of obtaining a fairness opinion, or appraisal of the loan portfolio value. After the fairness opinion is obtained, sale of the defaulted loans can proceed.

GERIATRIC SPECIALISTS

Question. The elderly are the fastest growing cohort of our population. There is expected to be nearly a 200% increase in Americans over age 65 by the year 2030. Yet the budget proposes no funding for geriatric education and training programs.

At the current rate of training geriatric specialists, will there be enough doctors, dentist, nurses, and other health professionals to meet the need in geriatrics?

Answer. National estimates in 1987 of full-time physician manpower in geriatrics range from a low of 118 to 250 faculty, to a high of 1,618 to 1,833, including clinicians, teachers and researchers. Projections indicate that by the year 2000 we will need 2,199 physician faculty (clinician and researchers) and 8,000 geriatric specialists (all clinicians). Currently approximately 100 geriatric fellows (geriatricians) per year graduate. The situation is similar in other health professions. Dentistry had about 20-25 gerodontists in 1987 and will need 1,500-2,000 in 2000. At least a doubling of the number of physical therapists is needed by 2020. The requirements in occupational therapy are similar. Thus the need for certain health professionals trained in geriatrics is much greater than the current rate of training will provide.

According to the March 1988 National Sample Survey of Registered Nurses, about 4,600 registered nurses have specialty preparation in geriatrics, either as clinical nursing specialists or nurse practitioners. In the 1986-87 academic year, there were 235 graduates from the master's degree programs focusing on geriatric nursing. There has been a significant increase in the numbers of nurses obtaining specialty preparation in the care of the elderly. For example, the number of those with masters or doctoral preparation degrees with primary focus in this area has tripled

between November 1984 and March 1988. The particular nursing needs of the elderly has become and will continue to remain an important focus of nursing education.

Question. If federal funding is discontinued, what other sources of funding have you identified for geriatric education and training programs?

Answer. Geriatric education and training programs are currently sponsored by VA, such as scholarships for study in the area of geriatrics, Geriatric Research Education and Clinical Centers and programs of the National Institute on Aging such as the Geriatric Academic Program. Also some private foundations are sources of support, such as the Hartford Foundation, Travelers Foundation, and the Robert Wood Johnson Foundation.

NATIONAL HEALTH SERVICE CORPS (NHSC)

Question. Is there a list of approved sites for priority placement of Corps doctors? What are the criteria for getting on that list? Please provide the Subcommittee a copy of the most recent list.

Answer. There is a list known as the High Priority Placement Opportunity List (HPOL) used in the assignment of NHSC obligors. The criteria for inclusion on this list are:

The site must be located in and serve the population of a Health Manpower Shortage area (HMSA);

The site must have a documented need for assistance from the NHSC in filling its manpower needs, generally as a result of not being able to recruit health manpower to meet its needs even though offering a competitive compensation package;

The site must be located in a community where access to health care is especially difficult;

The site must be part of an organized system of care with the expertise and mission to serve the underserved of the community.

Question. What are the pros and cons of giving preference in selection of health professionals for the NHSC (and IHS) loan repayment programs to those who have received part of their training in underserved areas?

Answer. The NHSC Loan Repayment Program currently gives competitive preferences to those applicants who prepared themselves for shortage area practice by taking part of their training in community health center settings. The advantage in this policy is that it enables us to select applicants better adapted to providing health care in the clinical conditions of these centers that are applicants whose training was limited to hospital-based settings.

However, whenever a group is excluded from selection by the use of preferences there is always the risk that the program will lose qualified, interested health professionals.

MATERNAL AND CHILD HEALTH

Question. By straight-lining the FY 1989 appropriation into FY 1990, how much in outlays would President Bush's flexible freeze proposal cut from the Maternal and Child Health block grant?

Answer. The Fiscal Year 1990 request for the Maternal and Child Health block grant does not include an increase for inflation, but we do not believe this will result in a reduction in services provided by the states. The block Grants are made to states to assure access to quality health services for mothers and children, to reduce infant mortality and the incidence of preventable diseases and handicapping conditions among children and provide services to children with special health care needs. States must provide $3 in State matching funds for every $4 in Federal funds, but many states have been providing a much greater matching ratio. Thus we believe that the states will continue to fund Maternal and Child Health programs on at least the FY 1989 level.

Question. Can you estimate how many low-income individuals would be denied access to care under the Bush proposal?

Answer. No sir, the nature of the block grant is such that States are not required to provide information at the level of detail.

Question. How are the activities of the Maternal and Child Health block grant coordinated with the Infant Mortality Initiative of the Community and Migrant Health Centers in order to avoid duplication of effort?

Answer. The infant mortality activities of the OMCH and the Community and Migrant Health Centers (CHCS/MHCs) are primarily coordinated through staff interaction and consultation. For example, staff of the OMCH were asked to develop the perinatal standards used by the CHCs/MHCs and provide technical assistance to them in the implementation of the initiative. OMCH staff assure through consultation and technical assistance that the CHC/MHC infant mortality initiative complements those of the ongoing maternal and child health block grants and that services provided in centers are not duplicative of those provided through the State programs. In some instances States do refer their patients to centers and reimburse for services provided.

NATIONAL HEALTH SERVICE CORPS

Question. How many Corps sited are there, including Community Health Centers,and freestanding sites, including rural hospitals?

Answer. Currently, there are 423 C/MHC sites, 617 freestanding sites. Of these 270 are urban and 770 are rural.

Question. How many doctors, dentists, and nurses are currently serving in the Corps?

Answer. There are 2,229 doctors, 103 dentists, 27 nurses and 23 podiatrists.

Question. How many sites is the program currently unable to serve, and how many Corps sites have lost physicians in the last two years?

Answer. We are currently unable to serve 475 sites of which 125 are C/MHCs and 350 are freestanding.

Question. How many Corps professional will fulfill their obligation this year? How many will fulfill their obligation in FY 1990?

Answer. In 1989 and 1990 we expect that 782 and 635 NHSC assignees, respectively, will complete their obligation.

Question. How many Corps recruits are you expecting to draw into the program this year? How many in 1990?

Answer. We expect to recruit 150 volunteers in 1989 and 200 volunteers in 1990, in addition, we expect 250 NHSC Scholarship and loan repayment obligors in FY 1989, and 72 loan repayment obligors in FY 1990.

Question. What can freestanding sites do to recruit doctors?

Answer. Freestanding sites are assisted by the Public Health Service recruitment program to help identify individual practitioners who may be interested in serving in these communities. If the site is located in an area for which it is extremely difficult to recruit, the NHSC would also approve the site for loan repayment as and added benefit to assist the community in recruitment.

NURSING STUDENT LOANS

Question. What is the default rate on nursing student loans?

Answer. The nursing student loan default rate as of June 30, 1988 is 3.0 percent.

Question. Why is there difficulty recruiting nurses into advanced practice roles? What are the restrictions on these loan programs?

Answer. We are not aware of any difficulties which are unique to recruiting nurses into advanced practice roles. The nursing student loan program assists nursing students undertaking a course of study leading to a diploma, associate degree, bachelor's degree, or graduate degree in nursing.

HEALTH PROFESSIONS SHORTAGES

Question. What is the current availability of medical and dental professionals specially trained to provide health care to our growing elderly population?

Answer. Although not the case just five years ago, currently nearly all medical schools (123 of 127) require their students to be exposed to courses in geriatric education.

Prior to the mid 1970s, there were no formalized geriatric training programs. Therefore, the majority of physicians currently practicing have not had formalized training. Moreover, during 1984 and 1985, no more than 8,000 of the 450,000 practicing physicians attended at least one day of continuing medical education devoted solely to geriatric medicine.

Physicians who are certified in primary care (i.e., internal medicine and family practice) are eligible to sit for an examination leading to a Certification of Added Qualifications in Geriatric Medicine. Over 2,400 physicians passed the first administration of the exam.

In 1987-1988, there were 103 geriatric medicine and geropsychiatry fellowship programs with 295 filled positions.

Future availability is dependent in part upon faculty able to teach geriatrics. Currently, faculty training projects in Geriatric Medicine and Dentistry have enrolled 44 physician participants.

Currently there are less than 50 dentists specially trained to provide health care to this growing elderly population. Approximately 25 dentists are now participating in the Federal grant program of faculty training in geriatric medicine and dentistry. Approximately 10 additional dentists per year receive advanced training in geriatric dentistry through specific post-doctoral training programs offered by the VA and several dental schools.

By the fall of 1988, 438 physicians and 154 dentists have received more than 40 hours of training in geriatrics through Geriatric Education Centers.

Question. What is the current information on the supply of podiatrists in this country? Will there be sufficient numbers of podiatrists to meet the needs of our elderly population for foot care?

Answer. The current population of podiatrists is estimated to be 11,500. This is based on the result of a 1984 National survey with adjustment for new graduates from the colleges of podiatric medicine and estimated death and retirement. It is not possible to project the requirements for podiatrists in the future due to the absence of adequate utilization data. The Health Interview Survey, which will be conducted by the National Center for Health Statistics in 1990, will have specific questions about foot problems and services sought for foot care. These data may enable us to make informed projections of the need for podiatric manpower in the future.

MALPRACTICE DATA BANK

Question. What is the status of the malpractice data bank?

Answer. On December 31, 1988, a 5-year, $15.9 million contract was awarded to establish and operate the data bank.

Question. When will it be operational?

Answer. The data bank is scheduled to become operational in the fall of this year.

COMMUNITY AND MIGRANT HEALTH CENTERS

Question. How do rural community health centers compare to urban centers in level of funding and scope of services provided? Do rural CHC's receive comparable funding allocations to urban CHC's of similar size serving similar population groups?

Answer: Rural funding from Section 330 represented 42 percent of the total grant funds awarded in FY 1988, although 61 percent of the grantees are rural CHCs. While the scope of services provided in each are comparable, rural CHCs tend to more of a medical model and may have to refer out more kinds of services.

Question. How many centers are receiving funds from the Infant Mortality Initiative this year? How many are located in rural areas? How do you evaluate the effectiveness of these infant mortality reduction efforts?

Answer: The $21 million available for perinatal awards in FY 1989 will support expanded case managed services in approximately 100 centers. Approximately 40 percent of this funding is spent in rural projects. The effectiveness of the program is measured in the fact that the pregnancies of 175,000 women who would otherwise not have services available to them are being managed, and medical services (including deliveries) are being provided through this initiative. The beneficial effects of early and continual care during high-risk pregnancies is well documented in medical literature.

Question. How do you assure that the additional funds centers receive for the infant mortality initiative, outreach to the homeless, and for treating AIDS patients are used as intended?

Answer: As with all funds awarded to grantees for a specific purpose, grantee reporting will be required to verify that the amounts awarded were used as intended. Well established tracking and reporting systems will be used to account for the expenditure of funds made available to CHCs and MCHs for services to AIDS patients, the homeless and for perinatal services.

Question. How are state and county health and other agencies involved in the Community and Migrant Health Centers programs? What role do state agencies play in the funding, operation, and oversight of health centers?

Answer. Since 1986, Bureau of Health Care Delivery and Assistance (BHCDA) has supported a grant with the National Association of County Health Officials (NACHO) to foster linkages between local health departments and Community and Migrant Health Centers (C/MHCs). NACHO maintains a data base that matches local health departments and C/MHC service areas and is assessing the type of linkages that presently exist. In 1990, NACHO and BHCDA will select a number of communities for more in-depth study of joint perinatal systems.

State agencies are involved with BHCDA primary care programs in several ways. First, State programs including Medicaid; Maternal and Child Health; WIC; Alcohol, Drug Abuse and Mental Health; Aging; AIDS; and health manpower frequently provide resources and grants to individuals C/MHCs. Second, BHCDA funds 31 Cooperative Agreements with State governments for the coordination of primary care resources. This mechanism allows joint Federal-State involvement in planning to meet primary care needs, improving effectiveness of individual centers and development of health care systems. Third, States comment on grant applications for C/MHCs under Office of Management and Budget specifications. Federal grant funds then flow directly from the Department to individual C/MHCs.

Question. How many centers provide health care to homeless people? How are these services coordinated with other programs serving the homeless?

Answer: A total of 102 Community Health Centers are involved in the Health Care for the Homeless program including 55 direct grantees and 47 subcontractors. Other centers are providing health care to the homeless but are not receiving funding under the Section 340 program. All Homeless projects are required to become actively involved in existing community coalitions or to establish community coalitions in order to more effectively serve the homeless population. Coalitions have been formed with a variety of entities including soup kitchens, shelters, welfare hotels, churches, legal aid societies, and state and local agencies such as health departments and departments of social services.

Question. Please provide the subcommittee with a listing of centers that are receiving additional grants, and the funding amounts for AIDS, homeless, infant mortality, etc.

Answer: The listings follow:

PERINATAL PROJECTS

Rural Health Centers of Maine Inc. Augusta, ME	$24,000
Hill Health Corp. New Haven, CT	138,880
Harbor Health Services (Dorchester) Boston, MA	69,431
Roxbury Comp Community Health Center Boston, MA	73,780
Northern Maine Rural Health Program Presque Isle, ME	60,000
Providence Ambulatory Health Care Providence, RI	130,200
South Cove Community Health Center Boston, MA	32,000
Family Health and Social Service Center Worcester, MA	73,780
SW Community Health Center, Inc. Bridgeport, CT	86,210
Community Health Services, Inc. Hartford, CT	54,746
Lynn Community Health Center Lynn, MA	83,328
Lamprey Health Care Newmarket, NH	69,440
Manet Community Health Center (Quincy) Quincy, MA	69,440
Charter Oak Terrace/Rice Hts Hartford, CT	40,000
Greater New Bedford Community Health New Bedford, MA	69,440
Mattapan Community Health Center Boston, MA	30,000
Greater Lawrence Family Health Lawrence, MA	138,880
Syracuse Community Health Center Syracuse, NY	112,840
East Harlem Clinic Human Services/Boriken New York, NY	69,440
Hunts Point Multi-Service Health Center Bronx, NY	130,200
William F. Ryan Health Center New York, NY	86,800

Newark Community Health Center Newark, NJ.....65,100
Rochester Primary Care Network Rochester, NY.....78,358
Family HC of Orange and Ulster Cos, Inc., Newburgh, NY...130,200
Westchester Health Network Mt. Vernon, NY.....261,029
Central Areawide Comp. Health Program Naranjito, PR.....65,751
Ponce Diagnostic Treatment Playa Ponce, PR.....60,760
East End Family Health Center St. Thomas, VI.....30,000
Bronx Ambulatory Care Network Bronx, NY.....409,261
Patillas RHI Patillas, PR.....30,000
Settlement Health and Medical Services New York, NY.....36,000
ODA Primary Care Health Center Brooklyn, NY.....60,000
CHC of Paterson Health Advocates Paterson, NJ..... ..69,440
Fredericksted Health Center St. Croix, VI.....30,000
Chinatown Health Clinic New York, NY.....50,000
Florida RHI Health Center Florida, PR.....55,000
Morris Heights Health Center Bronx, NY.....130,200
Carver Community Health Center Schanectady,NY.....60,000
LB Johnson HEalth Complex, Inc. Brooklyn, NY.....130,200
Anthony L. Jordan Health Center Rochester, NY.....48,650
Lares Health Center Lares, PR.....75,516
Jersey City Medical Center Jersey City, NJ.....164,920
Parkwest Health Service Baltimore, MD.....130,200
West Baltimore Family Health Baltimore, MD.....176,807
Somerset Co for Prog. Ent. (SCOPE) Princess Anne, MD.....104,160
Broadtop Area Medical Center Broad Top City, PA.....66,836
Hamilton Health Center Harrisburg, PA.....57,000
Central Virginia CHC New Canton, VA.....133,668
Eastern Shore Rural Health Systems Accomac, VA.....60,000
St. Charles Council St. Charles, VA.....76,291
Community Health System Sprague, WV.....104,160
Valley Health Systems, Inc. Barboursville, WV.....190,960
Intercounty Health Inc. Martinsburg, WV.....260,400
Tug River Health Assoc., Inc. Gary, WV.....30,000
York Health Corp. York, PA.....50,185
South Baltimore Family Health Baltimore, MD.....66,662
Brunswick Health Alberta, VA.....86,800
Covenant House Health Services Philadelphia, PA.....86,800
Peninsula Institute for Comm. Health Newport News, VA.....75,922
Glendale Area Med. Assoc. Coalport, PA.....26,000
New River Health Assoc., Inc.Scarbro, WVA.....130,200
Assoc. Program for Primary Care Baltimore, MD.....65,100
Philadelphia Health Services (PHS) Philadelphia, PA.....173,600
Baltimore Medical Systems Baltimore, MD.....86,800
Greater Philadelphia Health Action Philadelphia, PA.....151,900
Shenango Valley Primary Care Center Farrell, PA.....60,000
Spectrum Health Services, Inc. Philadelphia, PA.....122,220
Primary Health Services of NW Pennsylvania Erie, PA.....60,000
Montgomery Hlth Svs Inc./Lister Hill Montgomery, AL.....144,267
Florida Rural Health Services Frostproof, FL.....65,100
Borinquen Health Care Center, Inc. Miami, FL.....595,660
HEALTHSOUTH, Inc. Atlanta, GA.....131,068
West End Medical Center Atlanta, GA.....120,652
South Mississippi CHC Laurel, MS.....50,000
Mountain Comp. Health Corp. Whitesburg, KY.....91,140
Park Duvall Health Center Louisville, KY.....81,592
Central MS Civic Improvement Assoc. Jackson, MS.....151,900
Orange Chatham Comp Health Carrbor, NC.....109,997
Lincoln CHC/Durham Co. Hosp. Corp. Durham, NC.....65,100

Franklin C. Fetter Charleston, SC.....30,000
Beauford Jasper Comprehensive Health Ridgeland, SC.....147,560
Chattanooga Hamilton (Alton Park CHC) Chattanooga, TN....129,237
Rural Health Services Rogersville, TN.....81,158
SW Florida Hlth Ctr/Clinicas Migrant Ft. Myers, FL.....113,769
Collier Health Services, Inc. Immokalee, FL.....60,000
Bd of Co Commiss. Palm Beach Co. West Palm Beach, FL....130,200
Southern Rural Health Care Consortium Russelville, AL.....63,384
Coastal Family Health Center, Inc. Biloxi, MS.....173,600
West Tuscalossa Comm Hlth Center Tuscaloosa, AL.....60,000
Northern Kentucky Family Health Center Covington, KY.....69,451
Etowah Quality of Life Council, Inc., Gadsden, AL.....147,560
Franklin Memorial Primary Health Center Mobile, AL.....113,708
Boone Trail Medical Center Mamers, NC.....117,180
Society Hill Family Hlth Clinic, Inc. Society Hill, SC...140,825
East Padco Health Center, Inc. Dade City, FL.....110,670
Twin Co Rural Health Hollister, NC.....60,000
Rural Community Health Services, Inc. Parrotsville, TN....66,309
Britton's Neck Health Care Corp. Conway, SC.....60,000
Mobile Co Health Dept Fam Oriented PR Mobile, AL.....121,520
Lexington-Fayette Co Health Dept. Lexington, KY.....76,364
Central North Ala. Hlth Svcs Inc. Madison, AL.....130,200
Tri-County Health Center Troy, AL.....156,240
Tri-County Health Systems Greenville, FL.....48,500
Roberson Health Care Corp. Pembroke, NC.....65,100
Shawnee Hlth Svcs and Development Corp. Murphysboro, IL...60,760
Health Delivery Inc. Saginaw, MI.....112,840
Family Health Services of Darke Co. Greenville, OH.....78,291
Community Hlth Svcs of Northwest Ohio Fremont, OH.....60,534
Claretian Medical Center Chicago, IL.....130,200
Cincinnati Health Network Cincinnati, OH.....121,520
New City Health Center, Inc. Chicago, IL.....33,400
Indian Health Foard of Minnesota, Inc., Minneapolis, MN...86,800
Cordelia Martin HC/Ngbd Assoc of Toledo Toledo, OH.....86,800
Detroit Health Department Detroit, MI.....108,500
Indian Health Board of Milwaukee Milwaukee, WI.....90,381
Model Cities Health Center St. Paul, MN.....35,000
Crusaders Central Clinic Assoc. Rockford, IL.....133,312
Community Action Committee - Pike Co., Piketon, OH.....69,456
Westside Community Health Center St. Paul, MN.....87,366
16th Street Clinic/HOPE Milwaukee, WI.....95,480
Community Health Network, Inc., Indianapolis, IN.....164,920
Near North Health Center Chicago, IL.....113,603
Natchitoches Area Action Assoc. Natchitoches, LA.....225,680
Albuquerque Family Health Center, Inc. Albuquerque, NM...124,285
Community Health Centers/Mary Mahoney Oklahoma City, OK...60,000
Los Barrios Unidos Community Clinic Dallas, TX.....117,180
United Medical Services (Maverick Co) Eagle Pass, TX.....97,182
Hidalgo Co. Health Care Corp. Pharr, TX.....90,272
Gonzales County Health Agency, Inc.Gonzales, TX.....46,490
Comm Health Svc Agency Inc. of Hunt Co. Greenville, TX....95,480
Su Clinica Familiar/Catholic Charities Harlingen, TX.....108,500
Galveston Co. Coord. Community Clinic La Marque, TX.....147,560
Laredo-Webb Co Health Department Laredo, TX.....92,876
South Plains Health Provider Org., Inc. Plainview, TX....111,014
Martin L. King, Jr., Family Clinic, Inc. Dallas, TX.....82,352
Jasper-Newton Comm Health Center Newton, TX.....86,106
Centro de Salud Familia La Fe, Inc. El Paso, TX.....95,480

La Casa de Bueno Salud, Inc. Portales, NM.....54,863
Barrio Comp Family Hlth Care Ctr, Inc. San Antonio, TX...121,520
Mainline Health Systems, Inc., Portland, AR.....74,408
La Clinica de Familia, Inc. San Miguel, NM.....73,780
Centro Del Barrio Comm Hlth Ctr., Inc., San Antonio, TX...95,480
Presbyterian Med Svcs/Checkerboard Santa Fe, NM.....60,760
Morton Health Center Tulsa, OK.....104,159
Hunter Health Clinic Wichita, KS.....133,325
Samuel U. Rodgers Health Center, Inc. Kansas City, MO....217,000
Peoples Comm Health Clinic Waterloo, IA.....35,000
Caldwell Co Medical Aid Corp. Hamilton, MO.....31,096
Central Ozark Medical Center Richland, MO.....60,000
Peoples Clinic St. Louis, MO.....309,529
Charles Drew Medical Center Omaha, NE.....40,000
Denver Dept. of Health and Hospitals Denver, CO.....104,160
Plan de Salud del Valle, Inc. Fort Lupton, CO.....130,200
Sunrise Community Health Center Greeley, CO.....60,000
Salt Lake City Comm Health Center Salt Lake Ctiy, UT.....78,120
Comm Health of Colorado Springs Colorado Springs, CO.....50,000
La Clinica Campesina Lafayette, CO.....25,000
Santa Cruz Community Health Dept. Nogales, AZ.....126,728
El Rio Santa Cruz NHC Tucson, AZ.....151,900
Drew Health Foundation East Palo Alto, CA.....104,160
Clinica Sierra Vista Lamont, CA.....182,280
Watts Health Foundation Los Angeles, CA.....173,600
Merced Family Health Center Merced, CA.....182,280
West Oakland Health Council, Inc. Oakland, CA.....164,920
Mission Neightborhood Health Center San Francisco, CA.....71,176
North East Medical Svcs Inc. (NEMS) San Francisco, CA.....60,000
North County Health Project San Marcos, CA.....151,900
Waianae Coast Comprehensive HC Waianae, HI.....35,000
Northeast Valley Health Corp. Pacoima, CA.....173,600
La Clinica de la Raza, Inc. Oakland, CA.....118,048
West Contra Costa Community Health Care Richmond, CA... 121,520
Central Nevada Rural Hlth Consortium Babbitt, NV.....68,312
Memorial Family Health Center Phoenix, AZ.....160,580
Logan Heights Family Health Center San Diego, CA.....65,100
El Progresso del Desierto, Inc. Coachella, CA.....95,480
Arroyo Vista Fam Hlth Ctr Los Angeles, CA.....156,240
El Concilio de Madera Inc. Madera, CA.....73,780
Sequoia Comm Health Foundation Fresno, CA.....60,000
Southeast Oregon Rural Hlth.Network, Chiloquin, OR.....30,000
Anchorage Neighborhood Health Center, Anchorage, AK.....130,200.
Terry Reilly Health Services Nampa, ID.....138,880
Columbia Basin Health Association Othello, WA.....104,160
Central Seattle CHC Seattle, WA.....65,100
Puget Sound Neighborhood Health Centers Seattle, WA.....86,800
Multnomah Co Dept. of Human Services Portland, OR.....130,200
Community Health Care Delivery Tacoma, WA.....78,120

HOMELESS PROJECTS

Hill Health Corp New Haven, CT.....100,000
Providence Ambul. Health Care Providence, RI.....179,778
SW Community Health Ctr, Inc. Bridgeport, CT.....100,000
Charter Oak Terrace/Rice Hts Hartford, CT.....138,200
Westchester Health Network Mt. Vernon, NY.....341,804
Jersey City Medical Center Jersey City, NJ.....90,877

Primary Care Health Services Pittsburgh, PA.....200,844
Rural Hlth Corp of NE Penn Wilkes Barre, PA.....62,000
Valley Health Systems, Inc. Barboursville, WV.....106,640
Peninsula Institute for Comm. Health Newport News, VA....108,655
Midlands Primary Health Care Inc. Eastover, SC.....50,000
Central MS Civic Improvement Assoc. Jackson, MS.....50,000
Lincoln CHC/Durham Co. Hosp. Corp. Durham, NC.....94,563
Tampa CHC of Florida Tampa, FL.....170,000
Lexington-Fayette Co Hlth Dept. Lexington, KY.....66,283
People's Health Center Indianapolis, IN.....102,000
Cincinnati Health Network Cincinnati, OH.....150,000
Cordelia Martin HC/Ngbd Assoc of Toledo Toledo, OH.....175,000
Downriver Community Services Algonac, MI.....175,000
Crusaders Central Clinic Assoc. Rockford, IL.....150,000
Westside Community Health Center St. Paul, MN.....243,000
Indian Health Centers Indianapolis, IN.....89,916
Hamilton Family Health Flint, MI.....75,000
Community Health Centers/Mary Mahoney Oklahoma City, OK...50,000
Morton Health Center Tulsa, OK.....124,760
Hunter Health Clinic Witchita, KS.....136,151
Swope Pkwy Comp Health Center Kansas City, MO.....371,900
Community Health Care Inc. Davenport, IA.....80,000
Neighborhood HC Inc. (Grace Hill) St. Louis, MO.....361,161
Peoples Comm Health Clinic Waterloo, IA.....35,970
Broadlawns Medical Center Des Moines, IA.....35,000
Charles Drew Medical Center Omaha, NE.....81,070
Salt Lake City Comm Health Center Salt Lake City, UT.....108,300
Comm Hlth of Colorado Springs Colorado Springs, CO.....101,500
El Rio Santa Cruz NHC Tucson, AZ.....148,707
Family Health Foundation of Alviso Alviso, CA.....165,713
Drew Health Foundation East Palo Alto, CA.....96,840
Clinica Sierra Vista Lamont, CA.....27,047
Merced Family Health Center Merced, CA.....54,093
North East Medical Services, Inc. San Francisco, CA.....429,955
Nipomo Comm Med Center, Inc. Nipomo, CA.....50,000
Waianae Coast Comprehensive HC Waianae, HI.....74,216
West Contra Costa Community Health Care Richmond, CA.....54,093
Logan Heights Family Health Center San Diego, CA.....241,543
Sequoia Comm Health Foundation Fresno, CA.....50,000
Terry Reilly Health Services Nampa, ID.....100,000
Central Seattle CHC Seattle, WA.....321,540
NW Human Svcs. Inc. West Salem Clinic, Salem, OR.....80,000
Sea-Mar Community Health Center Seattle, WA.....124,760
Multnomah Co Dept. of Human Services Portland, OR.....170,877

Funding is requested for AIDS awards beginning in FY 1990. Therefore, a list is not available at this time.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

ORGAN TRANSPLANTATION

Question. As a result of a dismal track record by the past Administration in supporting the programs authorized by the National Organ Transplant Act of 1984, this Subcommittee has provided explicit instructions to the Health Resources and Services

Administration regarding the operation of the Office of Organ Transplantation.

In FY 1987, FY 1988, and FY 1989 the Committee specifically provided $1.4 million, $1.5 million, and $1.5 million respectively for the Office of Organ Transplantation. The Committee further instructed in the FY 1988 report (Senate Report 100-189) that this amount was to support "at least 10 FTEs, including "at least three with substantial expertise in the areas of organ retrieval and/or organ transplantation."

Please provide to the Committee a detailed accounting of how that money has been spent, how many FTEs are now at the Office, and how many of them had substantial expertise in the areas of organ retrieval and/or organ transplantation prior to coming to the Office.

Answer. By major object classes, program management funds appropriated for organ transplantation were expended as follows (dollars in thousands):

	FY 1987	FY 1988	FY 1989
Personnel Services	$ 500,000	$ 709,600	$ 734,400
Travel & Transportation	30,000	54,900	56,800
Other Services	725,000	580,600	600,900
Equipment	75,000	29,000	30,000
All Other	70,000	57,900	59,900
	$1,400,000	$1,432,000	$1,482,000

There are currently 10 FTEs in the Division of Organ Transplantation; 7 professional and 3 support staff. Of the professionals, 3 have had four or more years experience in the area of organ retrieval and organ transplantation. One professional staff member was formerly a clinical organ procurement coordinator and professional health educator for a certified organ procurement organization.

The office relies heavily on the organ procurement and transplantation community for expert advice on the issues confronting government in this field. For example, the office recently held a mini-workshop with experts in minority education/procurement to help develop a strategy for the office to educate minority groups about the critical need for donor organs. Whenever the office undertakes special initiatives requiring the expenditure of public funds, it involves the organ procurement and transplantation community to help assure that the funds are directed to where they can do the most good.

Question. Last year Congress reauthorized the National Organ Transplant Act, demonstrating its continuing commitment to these programs. The reauthorization law calls for FY 1989 spending of at least $8 million. The Reagan FY 1990 budget would slash current support for the national transplant program by 70 percent. By failing to send up a revised proposal, the Bush Administration appears to accept this position as well. Is that assumption correct?

Answer. The Fiscal Year 1990 request was not changed as a result of the Bush Administration review of the Reagan budget proposals. The budget request, which includes funds to continue the National Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, indicates our support for these activities. We do not believe that funds are necessary for grants to organ procurement organizations as they are supported through the end stage renal disease program and reimbursement from other third party payors. In fact, Aetna, the Medicare fiscal intermediary for organ procurement organizations reports that independent OPOs were reimbursed more than $51 million to cover kidney acquisition costs in FY 1988.

Question. Thirty-seven million Americans lack health insurance of any type and tens of millions more have inadequate health insurance. Those are statistics we are all familiar with. While all Americans have been asked to consider giving permission for organ donation, many Americans would be turned down for a place on the national transplant waiting list because they couldn't come up with the $100,000 guarantee virtually every transplant program requires.

I have introduced legislation to address the issue of financing of organ transplants. But until we have a more rational system of financing organ transplants, I believe the Office of Organ Transplantation can do more to assist the many American families that have been told a loved one will be allowed to die unless $100,000 is quickly raised.

I would like to see the Office of Organ Transplantation use some of its resources to assist families of transplant candidates. At the very lease the Office could set up an 800 phone number and hire a couple of social workers to assist families.

I request that the Office submit to the Committee a written plan detailing a program within the Division of Organ Transplantation that will help these families.

Answer. We do not believe that the addition of social workers to the staff of the Division of Organ Transplantation is necessary. Two organizations, the United Network for Organ Sharing, and the American Council on Transplantation both provide toll free phone service to assist potential transplant recipients and their families, as well as the general public.

The Division has sufficient staff and already provides assistance to transplant families by referring them to appropriate transplant programs, OPOs, State Medicaid programs, and voluntary health organizations.

AIDS

Question. Funding for the Education and Training Centers (ETCs) does not allow for expansion between 1989 and 1990. As the geography training widens, how will the ETCs adapt to this changing environment?

Answer. Although some of the Education and Training Centers are well on their way and may need greater resources, other ETCs

which are just recently funded and have not fully developed their programs in continuing education, clinical training or curriculum development and therefore do not require increased resources at this time. We believe we can balance these different needs with a constant budget.

Question. The Administration requests an additional $11 million for AIDS-related primary care provided by community and migrant health centers. How many HIV-infected patients do the community health centers see each year? Is care for these patients more costly than care for the average health center patient? Will these additional funds adequately cover the additional cost?

Answer. The Bureau of Health Care Delivery and Assistance is preparing an analysis of the impact of providing HIV-related services on C/MHC's that will also provide an estimate of the demand for HIV related services. However, by our more conservative estimates; in the pool of 6 million C/MHC users 55,000 are infected with the virus (the percent diagnosed and treated for HIV related conditions unknown) and 11,000 Health Care for the Homeless Program users carry the AIDS virus. These numbers are doubling every 15 months. Thirteen thousand of these people have had the disease for some time and are expected to exhibit symptoms within 1989 and an unknown number of asymptomatic individuals will come forward for testing, and extensive counseling. From analysis of centers in New York, New Jersey and Boston it is clear that people with HIV require substantially higher numbers of visits, longer visits than other center patients, and a broader array of services. The budget request will support a demonstration of the efficacy of the provision of HIV related services in the C/MHC sitting.

Question. What has been the impact of AIDS on the public hospital system? What has been the level of unreimbursed or inadequately reimbursed care for AIDS patients? What impact has this had on the quality of care or access to care provided to other low-income individuals seeking medical services? Does HRSA have any recommendations regarding how the adverse impact of AIDS can be reduced.

Answer. There is no question that AIDS has had a significant impact on the public hospital system. Some estimate that as many as 20 percent of AIDS patients have no health insurance and are not eligible for Medicaid, thus placing a large burden on the public hospital system. According to a recent article in Medicine and Health (3/20/89), most public hospitals run a deficit related to caring for AIDS patients. Miami's Jackson Memorial Hospital has seen its AIDS care deficit double each year--from $3 million last year, to $6 million this year to an anticipated $12 million next year.

Addressing the problem of the uninsured AIDS patient requires examination of a wide range of options including changes to the financing system, more widespread use of risk pools and further development of alternatives to hospitalization.

The impact of this on other low-income individuals seeking medical care has not been assessed systematically. However, there is anecdotal evidence that a large number of AIDS patients seeking care at public hospitals that already have very high occupancy rates

is leading to overcrowding and longer waits for nonemergency services

These pressures on large urban hospitals are part of the reason why public hospitals in such cities as Miami, Boston, and Dallas have led efforts to develop comprehensive, case-managed systems of community-based care for HIV-infected people. The development of these systems, which is the primary purpose of the HRSA Service Demonstration Projects, promotes the use of outpatient and community-based services as more appropriate and less expensive alternatives to acute hospital care. Over the last two years, the length of hospital stay for AIDS patients has been declining in many cities, in part because of the increasing availability of community-based alternatives to inpatient care. As the number of people with AIDS and HIV infection grows, continuing this beneficial effort will require expanding these systems of care in the cities that already have them, and establishing such systems in other cities. To date, HRSA Service Demonstration Projects have been established in 21 U.S. cities with high numbers of AIDS cases.

Question. Several of the early service demonstration grants will be expiring in FY 1989. In the professional judgement of HRSA, is it necessary to continue these grants to fully accomplish the objectives of these demonstrations?

Answer. Yes. The existing service demonstration projects will require some federal assistance. This will enable these projects to continue development of effective ways of dealing with the rapid growth and changing character of the HIV epidemic, with difficult service development and coordination problems, and with newly available therapies, including new expensive drug therapies.

At the outset, the epidemic affected primarily homosexual and bisexual men. There were no effective drugs or therapies to treat HIV infection, and care was given primarily in acute care settings. In this period, the emphasis of the service demonstration projects was on developing alternatives to hospital inpatient services and effective ways to link services to improve the continuity and quality of care. While a more appropriate array of services now is available to HIV-infected people in many communities, further efforts are needed to develop certain services: especially long term care and residential care, better linkages among an increasingly complex set of services and providers, and ways of dealing with deficiencies in the financing of serious chronic illness.

Currently, the HIV-infected populations growing most rapidly are intravenous drug abusers, women, and children, most of whom are members of racial or ethnic minorities. The service needs, social support systems, cultural characteristics, outreach needs and financial resources of these populations are very different from those faced earlier by most service demonstration projects. New approaches need to be developed to increase access to services and linkages among services for these populations.

Finally, sharp increases in the number of people with AIDS and HIV infection require development of service delivery networks on a much larger scale. New approaches are needed to coordinate services and deal with the inability of volunteer-provided support services

to handle much larger infected populations in the cities that received early service demonstration grants. Additionally, cities with service delivery and financing systems substantially different from those in cities initially most heavily affected will need assistance to develop suitable HIV service networks.

Question. What is the level of evaluation for the demonstration programs? Does it need expansion? Has the advisory committee mechanism created to translate the lessons of the demonstration programs into the programs and policies of other federal agencies been successful? What cooperation and information exchange has there been between HRSA and other agencies such as HCFA regarding the demonstration projects?

Answer. Two contracts have been awarded to evaluate the original four projects. One evaluation study is assessing the ability of these projects to effectively organize the non-acute community services needed by people with AIDS. The second will measure and analyze the utilization and costs of services at those sites. The results of these evaluations must be reviewed thoroughly before the need for expanded evaluation can be determined.

The advisory committee is now in place. The status of HRSA HIV programs will be shared with the advisory committee.

The HRSA Advisory Committee also includes other agencies, including HCFA, in planning, managing, and evaluating the service demonstration program. This occurs through a variety of mechanisms including advisory panels, technical review committees, and the Subgroup on Patient Care/Health Service Delivery, a component of the PHS Executive Task Force on AIDS.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

HEALTH PROFESSIONS

Question. The recently enacted Omnibus Health Act (P.L. 100-607), authorized a separate appropriation for a health professions training program in our dental schools. How much does the FY 1990 budget proposal include for this program?

Answer. No funds were requested for the General Practice Dentistry Training program (Sec. 785) for FY 1990.

Question. How much was in the FY 1989 appropriation?

Answer. The FY 1989 appropriation was $2,623,000.

Question. Could HRSA effectively use $6 million in this program for FY 1990?

Answer. Yes, HRSA could effectively use $6 million for the General Practice Dentistry Training program in FY 1990. The demand for advanced training in general dentistry still exceeds the capacity of existing training programs.

Question. How would HRSA spend $6 million if that amount were appropriated?

Answer. HRSA would stimulate a response to the advanced general dentistry grant program announcement, particularly among hospitals that are located in underserved urban and rural areas. Funds would be directed toward increasing the number of training positions and supporting the development of training experiences in the care of special population groups as the elderly, handicapped and HIV infected. HRSA would also support faculty development efforts as to prepare individuals to assume director and leadership roles in advanced general dentistry programs.

Question. The FY 1990 budget proposes to eliminate all federal funding of health professions training programs. Yet, the Congress authorized these and other programs last year in the Omnibus Health Act. In fact, rather than cutting back on these programs, Congress sought to restore its commitment to other health professions such as medical technologists and others. How much did HRSA request for health professions training programs in its FY 1990 budget submission to the Public Health Service?

Answer. HRSA requested $239.6 million for health professions training in its FY 1990 budget submission to the Public Health Service.

Question. The Omnibus Health Act reauthorized the community health center program and, in fact, increased the authorization level for this program. While I understand the FY 1990 budget includes an increase for the infant mortality initiative, the budget proposes a consideration was given to increasing the health center program? Did your original budget request include an increase for this program?

Answer. Throughout the budget process all programs are given consideration for increase and/or decrease. As you point out, an increase was provided for the Infant Mortality program and increases are also included for the Homeless and AIDS programs which will support services for the underserved as would additional funds for CHCs. In part, because of these increases in the highest priority areas, the request to the Office of Management and Budget did not propose an increase for this program.

AIDS

Question. Why is the FY 1990 budget for pediatric demonstration programs frozen when the incidence of pediatric AIDS is growing? What percentage of pediatric cases are not being reached with the demonstration program? Are there communities with high incidence of pediatric AIDS which will not be able to establish a demonstration program?

Answer. Within current budget constraints difficult choices had to be made and the decision to continue the Pediatric AIDS program at basically the same level as in 1989 was based on the newness of the program and the time needed to establish projects and evaluate, to some degree, their effectiveness. We expect that from 1988 to 1989 the program will double in size. The two years will give us a good start and help us to carry out appropriate

demonstration strategies. It is not the intent of this program to provide a comprehensive service base for all pediatric cases but rather to produce models of service which can be supported by State and other non-federal resources. We are supporting demonstrations in the high incidence areas, however, as stated the intention is not to serve all pediatric cases through these activities.

Question. One of the challenges faced by the research community in achieving a broader demographic base for its clinical trials is the lack of access that poor and minority groups have to primary care facilities able to perform research. Has HRSA made any attempt to link some of its primary care support for AIDS with the research efforts at NIH?

Answer. The Bureau of Health Care Delivery and Assistance (BHCDA) is working with NIH in its effort to broaden the base of clinical investigations by including primary care physicians who are not affiliated with AIDS research efforts currently supported by NIAID. This pilot project will attempt to bring to community health providers administrative and methodologic support for this research and, at the same time, include in clinical trials more HIV-infected black and Hispanic persons and intravenous drug abusers, and more women at risk of HIV infection. The BHCDA is assuring that appropriate community health centers receive program announcements and other material on the NIH-sponsored Community Programs for Clinical Research on AIDS. The NIAID will assure that investigators interested in the research program are informed about community health centers and the potential role they can play in the program.

Question. HRSA receives an additional 25 FTEs for AIDS, or double the 1989 level. Will this be sufficient? The increase in AIDS FTEs is in contrast to the reduction of overall FTEs for HRSA agency-wide (from 2,069 to 1,926). What non-AIDS programs at HRSA will be adversely affected by this transfer of resources?

Answer. The Health Resources and Services Administration request for 50 FTEs for AIDS, is adequate at this time to meet the needs of the program.

The non-AIDS programs for the Health Resources and Services Administration will not be affected by the transfer of resources into the AIDS Category program. In FY 1990 the decrease in FTEs for non-AIDS program is due largely to the proposed elimination of Health Professions programs.

SUBCOMMITTEE RECESS

Senator ADAMS. The subcommittee will stand in recess until 9:30 a.m., Monday, May 1, when we will meet in SD-192 to hear from the National Institutes of Health.

[Whereupon, at 12:02 p.m., Tuesday, April 18, the subcommittee was recessed, to reconvene at 9:30 p.m., Monday, May 1.]

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1990

MONDAY, MAY 1, 1989

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:01 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin and Bumpers.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR

ACCOMPANIED BY:

DR. WILLIAM H. RAUB, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. JAMES D. WATSON, ASSOCIATE DIRECTOR, HUMAN GENOME RESEARCH

H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET

DR. ANTHONY S. FAUCI, DIRECTOR, NIAID AND ASSOCIATE DIRECTOR FOR AIDS RESEARCH

JOHN D. MAHONEY, ASSOCIATE DIRECTOR FOR ADMINISTRATION

DR. SAMUEL BRODER, DIRECTOR, NATIONAL CANCER INSTITUTE

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator HARKIN. Good morning.

The Appropriations Subcommittee on Labor, Health and Human Services, and Education will come to order.

This morning and in our session this afternoon, the committee will consider the fiscal year 1990 budget request of the National Institutes of Health for $7.5 billion, which is $384.6 million, or 5.1 percent, more than provided by the committee last year.

In the several months since I have been chairman, I have heard statements from many interested parties regarding the decline in the number of research grants. The fiscal year 1989 increase was 6.8 percent, and the year before it increased 7.8 percent.

The NIH budget has doubled since 1980. Since I entered Congress in 1974, the budget has grown from $1.9 to $7.5 billion.

This morning, I will be interested to hear from Dr. Wyngaarden the reasons that with increasing funds we are funding fewer and fewer research grants. I will be interested to learn what can be done about the growth in the size of research project grants, or if, in fact, that ought to be a concern of ours.

I am concerned that as we have fewer and fewer grants awarded, our interest in having grants awarded across the country to quality institutions in all areas might be compromised.

The growth of NIH over the years underscores not only the compassion of the Congress for the health of the American people, but I might also add the very high regard in which NIH itself is viewed. Clearly, the National Institutes of Health is the world's leading biomedical research organization. We can all take pride in the progress and achievements that we have made. Medical research has made it possible to conquer many of the worst killers of a generation ago, including tuberculosis, pneumonia, rheumatic fewer, and many others.

In the hearings today, the committee will hear about the biomedical research challenges that we now face. We need to continue to make progress in cancer, stroke, heart disease, and AIDS. We need to unravel the mystery of Alzheimer's. We need to reverse the scandalously high infant mortality rate in the country.

These are some of the challenges that NIH and the biomedical researchers across the country now face. This committee wants to support this process by providing an adequate level of funding.

The first session this morning will permit us to discuss some overview issues with Dr. Wyngaarden.

The committee wants to learn of the NIH proposed response to scientific fraud and how that problem can be addressed. Also, we want to follow up on discussions started last year regarding the procurement system in NIH. Last year, we heard from the Inspector General that $26 million could be saved each year with system reform in procurement.

I am concerned that we see none of these savings reflected in the fiscal year 1990 budget. Clearly, we cannot afford to waste precious dollars that could be devoted to research that would help save lives.

Dr. Wyngaarden, I would like to just say a few words to you personally at this point.

Under your stewardship the National Institutes of Health has continued to awe the world with its accomplishments. We are all sorry to see you move on, and I say that personally from my own standpoint. I know that all my colleagues join me in wishing you the very best. Indeed, under your stewardship, the National Institutes of Health has indeed reached the pinnacle of its high regard by the American people, indeed by the medical community around the world.

PREPARED STATEMENT

Again, Dr. Wyngaarden and all of you, welcome to the subcommittee. Your full statements will be included in the record.

Dr. Wyngaarden, if you would just go ahead and summarize your statement, I would be most appreciative.

[The statement follows:]

STATEMENT OF DR. JAMES B. WYNGAARDEN

Mr. Chairman, it is my privilege to appear before you and the members of the Subcommittee to present the President's budget proposal for the National Institutes of Health. I will also take this occasion to tell you of research programs that we feel will be of special interest and to report on our stewardship as the principal Federal agency for biomedical research. My testimony, and the presentations by the heads of the constituent units of the NIH, will provide a general outline of our current plans and will present some examples of significant new insights into the biological sciences--knowledge that is being translated into better means for prevention and treatment of disease and disability. In my presentation I will refer briefly to the scientific and organizational implications of certain new programs; mention some current issues; and outline the FY 1990 budget proposal.

Before presenting my formal statement, I wish to express congratulations to you Mr. Chairman upon you assumption of the leadership of this important subcommittee, and thank you for the interest you have already shown in the NIH by your visits to the campus. We are immensely pleased to have you and the other members of the committee come to Bethesda to learn first-hand about our people and our activities.

By way of summary permit me to characterize the FY 1990 proposal for NIH as an expression by the Administration of its concurrence in the view, long espoused by the scientific research community that basic biomedical research should be a priority. The Administration is also committed to applied research on such priority topics as AIDS, and an area of unique scientific promise, human genome mapping. The proposal also shows recognition of the role research training plays in attracting new talent to research careers. Finally, the Administration proposes to maintain support of applied and developmental research.

In discussing our new programs, I first will mention the Human Genome Initiative. The NIH has supplied much of the impetus for the development of

new techniques that make possible the construction of high resolution genetic and physical maps of the total genetic endowment, or genome, of any organism of interest, including man. Ultimately we expect to advance to a determination of the complex sequence of the DNA of all of the constituent genes. In addition to the enormous amounts of biomedical information and better understanding of the role of genes in human disease that will come from this effort, many important scientific and technological advances can be expected, having both basic and commercial applications.

Such fundamental genetic research is providing a better understanding of inheritable diseases ranging from juvenile myoclonic epilepsy and Tay-Sachs disease to Duchenne muscular dystrophy. From recent research a new means has been developed for diagnosing hemophilia through direct analysis of the genome. In addition to facilitating carrier testing and prenatal diagnosis of hemophilia, this method can be used to identify genetic susceptibility to environmental agents of disease. The potential for new applications of advanced genetic research is essentially unlimited.

As we took the initial steps in developing the human genome program, it became clear that for the NIH to continue to exercise leadership in this endeavor we must establish an organizational focus to direct the project and to coordinate it within the NIH, with the National Center for Biotechnology Information of the National Library of Medicine, with other Federal and non-Federal agencies, with industry, and with various national and international scientific organizations. Accordingly, the NIH Office of Human Genome Research was created within the central administration of NIH. Dr. James D. Watson accepted my invitation to head the program as the first NIH Associate Director for Human Genome Research. Dr. Watson brings to the position the experience of his unmatched career as a scientist and scientist-administrator, and the pioneering vision that has brought him worldwide respect and recognition through the Nobel Prize and in many other ways. I am delighted that the FY 1990 budget proposes that $100 million be devoted to the Human Genome project.

Another highlight of the FY 1990 budget proposal is the substantial increase requested for the support of research on acquired immunodeficiency syndrome. While the FY 1990 budget proposes consolidation of all funds for AIDS in the Office of the Assistant Secretary for Health, the estimate for research through the NIH is $752.7 million, an increase of $149 million over the FY 1989 estimate. This increase will permit research on AIDS to continue to expand in vaccine development and therapeutics, building upon such initial advances as lengthening the life expectancy of AIDS patients through the use of AZT, other drugs in combination, and improvements in the treatment of opportunistic infections.

NIH-supported researchers have developed a highly sensitive method for the detection of the AIDS-causing virus. The polymerase chain reaction technique has made it possible to identify HIV genetic sequences in infected individuals before they are positive to antibody tests. This new technique is also expected to play an important part in the screening of blood donors as well as in efficacy testing for drugs and vaccines. In the area of therapeutics the NIH is simultaneously pursuing two avenues of anti-retroviral drug development--the screening of large numbers of existing compounds and the designing of targeted agents that can interfere with the life cycle of the virus.

The plan for FY 1990 is the most comprehensive approach yet developed to bring the full resources of biomedical research to bear on the problem of AIDS. To assist in setting priorities, and to coordinate the widespread and complex activities, we have created a new unit within the Office of the NIH Director, headed by the Associate Director for AIDS Research, Dr. Anthony Fauci, who serves concurrently as Director of the National Institute of Allergy and Infectious Diseases.

The use of the gene transfer technique is another exciting development. Scientists at the NIH will soon begin using for the first time this technique as a means for learning why a promising new form of cancer treatment seems to be effective in some patients and not in others. The

experimental cancer treatment developed by Dr. Stephen Rosenberg of the National Cancer Institute makes medical use of certain cells produced in the bodies of cancer patients. These cells are capable of killing a patient's tumor cells while sparing normal cells. The tumor-fighting cells that are removed from the body, treated with a growth factor and reintroduced appear to produce remission in some patients, but not in others. In the hope of understanding why this is the case, the researchers have wanted to trace the cells after administration. The gene study is designed to label the cells for tracking in the body.

In the first experiment a bacterial gene that produces harmless but recognizable characteristics will be inserted in tumor-fighting cells from ten patients with advanced melanoma--a deadly type of skin cancer--and the altered cells will be returned to the patients from whom they were taken. Cells from a patient's blood or biopsied tissue that contain this marker can be identified easily, and from this information it is hoped that the therapy can be improved. Ultimately, the scientists hope to use the gene transfer technique for cancer therapy.

Mr. Chairman, at the time I appeared before this Committee last year, I reported that the Institute of Medicine of the National Academy of Sciences (IOM/NAS) had been asked to do an independent evaluation of various strategies to strengthen the scientific excellence of the NIH intramural laboratories. The IOM/NAS study, A Healthy NIH Intramural Program examined the proposed alternatives and made several recommendations designed to improve the competitive position of our intramural programs with respect to recruitment and retention of senior scientists. Time does not permit me to comment on the report item by item, but I will say that in general I am gratified by the results. The study reaffirmed the importance of the intramural program, and in commenting on its high quality said there is no need for radical changes.

In this context, the Administration seeks to foster fair compensation for intramural scientists and scientists supported by NIH who work in non-profit and pharmaceutical laboratories. Appropriation language regarding extramural compensation is proposed, and additional proposals based on the Institute of Medicine Report are under study as we analyze how best to use its findings to strengthen our intramural program.

As biomedical research has become more complex and intellectually demanding, the training of researchers has become more and more a primary concern. As an example of expanded need, growth in the field of biotechnology will depend upon adequately trained scientific and technical personnel who have been trained to apply physics, mathematics and chemistry to such problems as biological structures at the molecular level. Special interdisciplinary training programs have been developed to meet the new needs of biotechnology. Mr. Chairman, your immediate predecessor was deeply interested in this subject, and encouraged us to develop the post-doctoral and senior fellowships in biotechnology. Certain of these have been named in his honor, and shortly we will be announcing the first Lawton Chiles Fellowships.

While all of our training programs are offered to provide necessary training, they also play a critical role in attracting able young scientists into research careers. After careful consideration the NIH recommended and the Public Health Service approved an increase in the stipends for trainees to provide a level of support adequate to attract the best research trainees, even though such an increase was expected to result in a reduction of the number of trainees. For the trainees predictability is of critical importance for normally the potential researcher has only a limited time when research training can be fitted into a complex and active career. We are taking all feasible steps to ensure that the training grants due for renewal in FY 1989 do not bear the full burden of the requisite reduction in the number of trainees. One such measure was to maintain tuition payments for FY 1989 at the FY 1988 level, and another possibility is to request a reprogramming of funds.

Mr. Chairman, the overall FY 1990 budget request for the National Institutes of Health is $6,776.7 million, an increase of $233.3 million or 3.6 percent over the comparable FY 1989 budget. The request places additional emphasis on basic biomedical research, providing an increase of 6.6 percent in this category of activity. For the first time the budget includes a separate request for the new National Institute of Deafness and Other Communication Disorders.

In the FY 1990 request all funding for AIDS is consolidated in a special account in the Office of the Assistant Secretary for Health. Consequently, in the following discussion of the FY 1990 budget for NIH, and in comparisons with FY 1989, the estimates for AIDS will be excluded.

Investigator-initiated research continues to be accorded the highest priority in the NIH budget. The FY 1990 request will support a total of 19,773 research grants as compared to 20,130 in the current fiscal year. The support for research project grants would be increased by 5.7 percent over the current year and would total $4,034.5 million.

The request will support 4,556 competing research project grants. This is a decrease of 572 competing awards from the number to be made this year. The number results from our effort to achieve a balance between levels of downward negotiation required and the number of grants to be supported. The awards include as many as 100 research grants that are planned to be funded from the Director's Discretionary Fund, an amount of $25 million requested for FY 1990 that can be allocated to the individual NIH components and will allow the NIH to be more responsive to emerging research opportunities and health priorities.

The NIH request for research centers of $551.7 million would support 572 centers. Due to the high priority attached to General Clinical Research Centers, as well as the higher costs associated with clinical research, these awards will receive an aggregate increase of 3.4 percent. The total

allocated to all other research center awards will be reduced slightly from the FY 1989 level.

The FY 1990 request includes an 8.3 percent increase for the research career development programs and a 5.1 percent increase in research training programs.

In recognition of the importance of programs for mincrities and small colleges, a 3.4 percent increase has been provided for the Minority Biomedical Research Support Program, the Minority Access to Research Careers Programs, the Research Centers in Minority Institutions Program, and the Academic Research Enhancement Award Program.

The excellence of NIH scientists and the intramural facilities, including the Warren Grant Magnuson Clinical Center, afford many unique research opportunities. The FY 1990 request for $733.9 million provides an increase for intramural research of 6 percent over the FY 1989 level. This increase will be used to cover the costs of administrative increases and with improved efficiency in procurement practices will offset the effects of inflation on the costs of basic laboratory and hospital supplies and equipment.

Thank you. I would be pleased to respond to any questions you may have.

BIOGRAPHY OF DR. JAMES B. WYNGAARDEN

Born October 19, 1924, East Grand Rapids, Michigan

Education Calvin College, 1942-43, Western Michigan University, 1943-44. M.D., University of Michigan Medical School, 1948.

Professional History Intern and Resident, Massachusetts General Hospital, Boston, 1948-52. Visiting Investigator, Public Health Research Institute of the City of New York, New York, 1952-53. Investigator, National Heart Institute, NIH, 1953-54, National Institute of Arthritis and Metabolic Diseases, NIH, 1954-56. Clinical Instructor in Medicine, George Washington University, Washington, D.C., 1954-56. Associate Professor of Medicine, Duke University Medical Center, Durham, North Carolina, 1956-59. Associate Professor of Medicine and Biochemistry, Duke University, 1959-61. Professor of Medicine and Associate Professor of Biochemistry, Duke University, 1961-65. Visiting Scientist, Institut de Biologie-Physiochemique, Paris, 1963-64. Frank Wistar Thomas Professor and Chairman, Department of Medicine, and Professor of Biochemistry, University of Pennsylvania School of Medicine, Philadelphia, 1965-67. Physician-in-Chief, Medical Service, Hospital of the University of Pennsylvania, 1965-67. Frederic M. Hanes Professor and Chairman, Department

of Medicine, Duke University, 1967-82. Physician-in-Chief, Medical Service, Duke University Hospital, 1967-82. Chief of Staff, Duke University Hospital, 1981-82. Director, National Institutes of Health, 1982-present.

Professional Organizations American Academy of Arts and Sciences, American Association for the Advancement of Science, American Board of Internal Medicine, American Clinical and Climatological Association, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association, American Society for Clinical Investigation, American Society of Biological Chemists, Association of American Physicians, Endocrine Society, National Academy of Sciences, NAS/Institute of Medicine, Southern Society for Clinical Investigation, Sigma Xi.

Honors, Awards University Scholar in Professional Schools (Medical), University of Michigan, 1946. Alpha Omega Alpha (University of Michigan), 1947. Cum laude with First Honors, University of Michigan, 1948. Dalton Scholar in Medicine, Massachusetts General Hospital, 1948. Honorary Membership in the Italian Society of Rheumatology, 1961. Consultant to the Office of Science and Technology, Executive Office of the President, 1966-72. Sesquicentennial Award, University of Michigan, 1967. Appointed to the President's Science Advisory Committee, 1972. Modern Medicine Award for Distinguished Achievement, 1974. Election to the National Academy of Sciences, 1974. North Carolina Governor's Award in Science, 1974. Appointed to the President's Committee for the National Medal of Science, 1977-80. Founder's Medal, Southern Society for Clinical Investigation, 1978. The John Phillips Memorial Award, American College of Physicians, 1980. Honorary Membership in the Sociedad Medica de Santiago de Chile, 1981. Fellow of the Royal College of Physicians of London, 1984. Distinguished Alumnus Award, Western Michigan University, 1984. Election to Royal Academy of Sciences of Sweden, 1987. U.S.-Israel Binational Foundation Board of Governors, 1987. French and American AIDS Foundation Board of Trustees, 1987. World AIDS Foundation Board of Directors, 1987. Chairman, Biotechnology Sciences Coordinating Committee, OSTP, 1988.

Honorary Degrees University of Michigan, D.Sc., 1980. Medical College of Ohio, D.Sc., 1984. University of Illinois at Chicago, D.Sc., 1985. George Washington University, D.Sc., 1986. Tel Aviv University, Israel, Ph.D., 1987.

INTRODUCTION OF ASSOCIATES

Dr. WYNGAARDEN. Thank you very much, Senator Harkin, for your generous comments about the National Institutes of Health and about me personally. I do appreciate that.

Before we begin, I would like to introduce the other witnesses.

With me today are Dr. William Raub, Deputy Director; Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases and Associate Director for AIDS Research; Mr. John Mahoney, Associate Director for Administration; Mr. Richard Miller, Assistant Director for Budget; and Dr. James Watson, Associate Director for Human Genome Research.

FISCAL YEAR 1990 BUDGET REQUEST

It is a privilege again to appear before you and the subcommittee to present the President's budget proposal for the NIH. I will highlight the general outline of our current plans and some of our accomplishments and speak specifically to the 1990 budget proposal.

This budget lays particular stress on basic research, but continues to support such high priority areas as AIDS research and the Human Genome Mapping Project, as well as addressing the issue of research training and the support of applied and developmental research.

HUMAN GENOME INITIATIVE

I would like first to mention the human genome initiative.

As you know, the NIH has supplied much of the impetus for the development of new techniques and new knowledge that make possible the construction of a high resolution map of the total human genome of any organism, including man. Ultimately, we expect to

advance to the determination of the complex sequence of the DNA of all constituent genes. We believe that this information holds enormous potential value for the understanding of human disease, not only of those that are obviously inherited, but also the complex relationships that contribute to many common diseases, which we believe have genetic influences in many parts of the human genome.

This kind of research has already expanded our understanding of such diseases as myoclonic juvenile epilepsy and Tay-Sachs disease, and muscular dystrophy of various kinds. We expect that it will do the same for various common diseases.

As we took the initial steps in developing this program, it became clear that if we were going to exercise leadership in this field, we needed to organize ourselves somewhat differently. We established within the Office of the Director a new Office on Human Genome Research and appointed Dr. James Watson as the first NIH Associate Director for Human Genome Research.

As you know, Dr. Watson brings to that position a matchless career as a scientist and scientist-administrator. He is a Nobel Prize winner for his work, together with Francis Crick, on the structure of DNA, which has made so many of these new developments possible.

AIDS

We have also requested a substantial increase for research on the Acquired Immuno-Deficiency Syndrome, but that funding, as you know, is requested in the budget of the Assistant Secretary for Health. The figures that I will be presenting do not include the AIDS budget for the most part.

We have also established an office within the Office of the Director for coordination and direction of AIDS research, and that is headed by Dr. Fauci, as I have indicated previously.

SCIENTIFIC ADVANCES

We have a few advances that I would like to cite briefly. One of these has to do with the first authorized human gene transfer experiment into man.

Scientists at the NIH will soon be using a new technique to track cancer fighting cells in the body. This project is under the direction of Dr. Stephen Rosenberg of the National Cancer Institute. Tumor infiltrating lymphocyte cells are removed from the body, treated with a growth factor, and reintroduced into patients. In some patients, that treatment produces a remarkable remission, particularly in two kinds of cancer, cancer of kidney cells, called Renal Cell Carcinoma, and Malignant Melanoma.

The effects, while dramatic in some patients, are much less so, even nonexistent, in others. The reason for this disparity is not yet known.

One of the objectives of this new approach is to follow these cells to see where they go, to try to shed some light on the variable responses. To do that, a bacterial gene for neomycin resistance is added into these cells, and then they are restored to the body. This process does not make the treated cells more effective therapeuti-

cally, but it does provide a genetic marker that will enable us to follow these cells.

This process is also a prototype of a gene therapy that may be profoundly significant in the future.

That experiment has gone through multiple layers of review, both within NIH and within the FDA, and has been approved by all the necessary committees. It is likely to begin in the next several months.

IOM REPORT

Mr. Chairman, I reported to the committee last year that the Institute of Medicine of the National Academy of Sciences had been asked to do an evaluation of the intramural NIH program. Their report, entitled "A Healthy NIH Intramural Program," examined a number of alternatives for management and for structure that had been raised as possibilities by the Office of Management and Budget.

The distinguished panel, headed by President Shapiro of Princeton University, reaffirmed the importance of the intramural program, commented on its high quality, and did not advise any radical changes. It did make a number of important suggestions for improvement of the program, and many of those are now being implemented and are the basis for some proposed changes. Some of these changes would require legislative action. But we are gratified that the report was resoundingly complimentary of the program as it now exists.

TRAINING STIPENDS

We have a great concern also about training. We came to the point this past year of realizing that the stipend structure in the training programs was so noncompetitive that we were losing highly qualified young people.

After the Appropriations Committees had finished their work last year, we proposed, and the Assistant Secretary approved, an increase in stipends, which would be achieved by internal rebudgeting. We have done that, but without some compensatory changes, the stipend increases would reduce the number of trainees to be appointed.

We have maintained tuition levels at the 1988 level for the second year, in order to contain those costs, and we have also searched our programs for potential savings to offset the impact of this decision. A reprogramming request is currently under consideration at OMB. It has previously been approved by the Public Health Service and the Department. That would bring us up to about 85 percent of the number of new and competing trainees in 1989 that we had appointed in 1988.

FISCAL YEAR 1990 BUDGET REQUEST

The budget, as you know, is for $6.7 billion, exclusive of AIDS, and that represents an increase of $233 million, or 3.6 percent over the comparable 1989 budget. The investigator-initiated research project grants continue to be our highest priority. This budget

would support a total of 19,773 such grants, and the support for those projects would increase by 5.7 percent from the current year.

This request will support 4,556 competing research project grants. That is 572 less than the number in the 1988 budget.

The request contains $551.7 million for 572 centers. Owing to the high priority attached to the General Clinical Research Centers, that program would receive an increase of 3.4 percent. But most other centers would be at the 1989 level, or slightly below that.

We have increased the Research Career Development Program by 8.3 percent, and the Research Training Program by 5.1 percent. The Minority Programs have also been singled out for a 3.4 percent increase.

The Intramural NIH Program would increase by 6 percent, somewhat more than average, and those funds would be used to cover the costs of administrative increases and with improved efficiency in procurement practices will offset some of the effects of inflation on the costs of basic laboratory and hospital supplies and equipment.

Mr. Chairman, I would be pleased to try to answer any questions that you might have.

RESEARCH TRAINING

Senator HARKIN. Dr. Wyngaarden, thank you very much for that summary.

Let's start first with the training slots and stipends.

I have a question that staff has developed for me.

You say that you are going to reprogram some money to get back the slots up to, what, 11,600?

You had a reduction, as I understand it, from 11,600 to 10,300.

Dr. WYNGAARDEN. The figures I have would reduce the amount. In 1988, the total would be 11,183; in 1990, the estimate now would be 10,021, which would be a reduction of about 1,100 slots. This is inclusive of genome and exclusive of AIDS. So the figures would be a little less than yours.

Of that approximately 1,100, we would potentially regain 810 by the two maneuvers I described.

Senator HARKIN. What are those maneuvers again? Are we going to get the money for this? How much money do you anticipate for that?

Dr. WYNGAARDEN. We are talking here primarily about the new and competing traineeships. By looking carefully through the training program portfolio, institute by institute, some funds have been identified as savings from programs where perhaps not all the traineeships are being filled. That measure will increase by 225 the number of new slots that we could fund this year.

In addition, we have proposed a reprogramming of about $13 million, chiefly from the research project grant category. It would reduce those by about 20 new awards across NIH and, in addition, would increase the downward negotiation by approximately 1 percent on the noncompeting renewals.

That reprogramming would allow for 585 additional new trainees, new and competing awards, for a total of 810 additional training slots.

Senator HARKIN. So it is reprogramming of about $13 million. It is taking slots that aren't being utilized right now.

Dr. WYNGAARDEN. Yes.

Senator HARKIN. I don't quite understand that.

Dr. WYNGAARDEN. In some institutions there are training programs that might have five or six slots assigned to them. This year, by checking throughout the training program, we might have identified perhaps only four slots being used. One of the unused slots can be made available to some other program that is coming up competitively for renewal this year.

Senator HARKIN. Let me just get to the bottom line of this for next year. We have had a reduction in the number of slots. Our numbers are off a little bit because I had included the AIDS and the genome.

But your reprogramming and looking at the other slots will get you back up in 1990 to 11,000——

Dr. WYNGAARDEN. This would be in 1989.

Senator HARKIN. This is in 1989?

Dr. WYNGAARDEN. Yes; in 1989, the reprogramming would get us up to 10,831.

Senator HARKIN. To 10,831.

Dr. WYNGAARDEN. Yes; in 1989.

Senator HARKIN. And how much are you anticipating for 1990, then?

Dr. WYNGAARDEN. It would be 10,206 in the request for 1990, exclusive of AIDS.

Senator HARKIN. So we are down quite a bit?

Dr. WYNGAARDEN. We are still down from 1989 and 1988. Actually, that would be the smallest total number in probably 10 years or more. We are considering some further reprogramming in 1990 to raise that figure. We have not developed all of those details, as yet.

Senator HARKIN. Obviously, the pre-doctoral stipend was increased from $6,500 to $8,500.

Dr. WYNGAARDEN. Yes, sir.

RESEARCH TRAINING

Senator HARKIN. The post-doctoral stipend was increased——

Dr. WYNGAARDEN. They vary, but the average increase is about $1,500. They vary by year of experience.

Senator HARKIN. So that meant the numbers came down.

Again, I am trying to figure this out. I am charged with the responsibility for 1990, and am trying to figure out what should we do, if anything, to address this problem.

I mean, are 10,206 training slots enough for 1990, or should we try to look for some place to find some funds to get that back up?

Dr. WYNGAARDEN. We would reassess this problem when the total budget is available to us, and perhaps propose some reprogramming to raise that figure.

Senator HARKIN. You are saying that in your professional judgment, it should be raised back up?

Dr. WYNGAARDEN. Yes; it should. It should be raised by approximately 1,000 trainees.

Senator HARKIN. We will work with you on that and see what we can find when the budget comes through here.

HUMAN GENOME INITIATIVE

Let me talk about Dr. Watson's project, the human genome.

The largest single increase that we have seen in the budget is for this project.

Dr. WYNGAARDEN. Yes; that is correct.

Senator HARKIN. While this money is included in the National Institute for General Medical Sciences, I understand that NIH proposes to manage it out of the Office of the Director.

Dr. WYNGAARDEN. Yes, sir.

Senator HARKIN. I further understand that a NIH-sponsored conference last year suggested that spending for the Human Genome Project should be increased each year for 5 years, until it got up to $200 million per year.

Dr. WYNGAARDEN. Yes; that figure is correct.

Senator HARKIN. And be maintained at that level for 15 years, for a total of a $3 billion project.

I know it has been talked about as the "Manhattan Project of Life Sciences."

I guess what I am wondering about is this. Tell me about having the money in one institute but the management out of the Director's Office. Are there any problems there?

Dr. WYNGAARDEN. It has worked very well to this point. However, we have proposed to the Department, Mr. Chairman, that the next step be taken, namely, to create a National Center for Human Genome Research, convert the office to a center. The difference there is that a center would have greater independence. It would have its own appropriation, it would have its own council, and it would make its own awards.

That request is now being considered in the Secretary's office. The Secretary has the authority to create that kind of organization. Clearly, the Congress has that right also. That may be the next step.

Dr. Kirschstein, the Director of the National Institute of General Medical Sciences, is strongly supportive of that, and I know Dr. Watson is also.

Senator HARKIN. Do you mean a separate center?

Dr. WYNGAARDEN. A separate center, yes.

Senator HARKIN. A separate institute?

Dr. WYNGAARDEN. It wouldn't have that name because the human genome is a much smaller and more focused project.

Senator HARKIN. But it would be directly under the Director's Office, and it would be a center.

Dr. WYNGAARDEN. Yes; it would be a center. It would have the same independence as an institute, as the Fogarty International Center, or the National Library of Medicine, have.

Senator HARKIN. Is there not any other place? I mean, of all the institutes, is this where this most logically falls?

Dr. WYNGAARDEN. We think it is sufficiently different to warrant independence.

One of the differences is that this is a very highly targeted project in concept, and will require much more central management than the usual research portfolio would. We would use the same mechanisms, research grants, program project grants, and some centers around the country. However, the necessity for coordination of this program at the NIH level and with other agencies, for example, the Department of Energy, and even internationally, is quite different.

It also differs qualitatively in that the work done here is based less on individual hypotheses of scientists, which is the great strength of the extramural grant program of the Institutes, relating to their mission. Here there will certainly be room for that kind of individual initiative, and we need it. But the amount of central coordination and management is quite different from the usual portfolio.

We also want to keep separate this planned effort to map and then sequence the human genome from other kinds of genetic work, which we have supported for 30 or 40 years. That genetic work relates to the specific disease genes of interest to the categorical institutes.

The work will clearly be interrelated, but there are sufficient differences that compel us to make sure that the one does not compete inordinately with the other.

I don't know if Dr. Watson wants to elaborate on that or not, Mr. Chairman, with your permission.

HUMAN GENOME INITIATIVE

Senator HARKIN. I would like to call on Dr. Watson.

It is an honor to have you here. This is obviously a very big project.

There are two or three big projects out there that we are looking at over the next several years. This is the one in the life sciences. Obviously there is a super conducting, super collider, and there are a few others, space stations, a few other big projects out there that are going to take a long time to complete.

There will be a lot of debate surrounding this specific one. In my own reading of it, from a lay person's standpoint, there are arguments on both sides as to whether or not we should proceed, at how rapid a pace we should proceed, on mapping the human genome.

How important is it that we really push ahead very aggressively in this area?

Dr. WATSON. I believe it is extremely important.

Senator HARKIN. To what end?

Dr. WATSON. Understanding life, I think. The human genome is the set of instructions for human development. All the instructions come ultimately from the DNA.

Getting the instruction book provides an enormous opportunity to understand ourselves, not only when we function successfully but when we don't function successfully, which is often, because we don't have quite the right genetic instructions.

By going at the primary cause of so many diseases, we have a real chance of understanding them.

I think we have had enormous success, as Dr. Broder will explain to you later, in beginning to understand cancer because we can find the changes in the genetic material that give rise to cancer. Before that, it was really a black box that we didn't know how to get into.

There are still many other diseases, like manic depressive disease, schizophrenia, juvenile diabetes, probably some component of Alzheimer's, where we have no idea as to the fundamental cause. By understanding the genes, we have a chance.

In the case of Alzheimer's, specifically, I don't know of any other direct way to get at it, but to get at the gene on Chromosome 21, which confers the susceptibility to it, or makes it more likely to occur.

So, as a disease hunter, getting the genome is really what we want to do.

The program has been described as this massive working out of all the letters of the instruction, but, in fact, for the first 5 years, we really want to do high resolution physical maps, as our primary aim. We do not intend to sequence the human gene right now.

Senator HARKIN. You are looking for a specific gene?

Dr. WATSON. No; we want to get a general map of all the chromosomes, so that we can locate all the diseases—Huntington's disease, Cystic Fibrosis. We know approximately where they are, but we want to find the specific genes.

That really means having a very detailed idea of the structure of the chromosome, so we want to get what we call physical maps. We want to get all of the DNA in little bottles so we can say these bottles probably contain the Cystic Fibrosis gene, these bottles are where we should look for Alzheimer's, these bottles are where we should look for Huntington's.

That is the real work for us for the next 5 years.

The techniques are ready now to move from the research stage to a sort of production phase.

Senator HARKIN. OK. Let me ask you this.

What was your request for next year, $100 million?

Dr. WYNGAARDEN. For the genome?

Senator HARKIN. Yes.

Dr. WYNGAARDEN. Altogether, it is $100 million. It will be $99.1 million at NIGMS, and $900,000 in the Office of the Director.

Senator HARKIN. And that would increase every year until we got to $200 million? That was the plan before. They want to reach that level much sooner?

Dr. WYNGAARDEN. The recommendation of the National Academy of Sciences Committee was about $200 million per year for 15 years.

Senator HARKIN. Beginning right now?

Dr. WYNGAARDEN. We are certainly not asking for more than $100 million for next year. But I think Dr. Watson's estimate is we could reach the $200 million level profitably sooner than in 5 years.

Senator HARKIN. That's what I wanted to ask.

Dr. WATSON. Within 3 or 4 years. I should say we don't intend to do this research in one place in the United States. It will be spread out among a large number of leading research laboratories, universities, and medical centers.

These efforts will involve groups of 20 to 50 people, who can provide all of the techniques for getting the maps.

I see the program over the next 5 years as a program of research grants which are aimed at developing new technologies, and then a program of center grants where we use these technologies to get the resource, which is the structure of the genome.

Senator HARKIN. I understand you are asking through September 1991. So you are asking for a 2-year authorization, a 2-year appropriation?

Dr. WYNGAARDEN. Yes.

The funds are requested to be available for 2 years, which is not quite the same as a 2-year appropriation. I think the point that the administration makes there is that in case it is not possible to spend that much profitably the first year, the funds would be available to be carried over, and, I presume, applied toward whatever the 1991 request would be.

Senator HARKIN. Now, I'm going to have to make the argument on that. That is different from everything else. Is there anything else like that at NIH?

Dr. WYNGAARDEN. No, sir.

Senator HARKIN. Well, you'd better supply me with some ammunition here to argue for 2 years on this. I can hear it now: Well, if you can't spend it in 1 year, let them come back next year.

Dr. WYNGAARDEN. I believe Dr. Watson's current feeling is—and he can speak to this—that we could probably use all of the request in the 1990 fiscal year.

Dr. WATSON. We're developing a plan, and we're talking now to a number of potential places where this work could be done. These institutions will come in with proposals to us, and that will take roughly 6 to 9 months.

We will have to tell them they can do it. We have to have some feeling of whether the money is going to be appropriated before they are going to come in with a plan. We would hope we would have a large number of applications coming in roughly in the beginning of 1990.

We will then go through peer review and evaluate these proposals. We probably will be ready to give out the money sometime late in fiscal 1990, but we might fail by a couple of months.

The 2-year appropriation is really because of the time necessary to plan this program. It's different from the ordinary research grants.

Senator HARKIN. I understand.

There is a panel that was supposed to have been established, an advisory panel. Did that happen?

Dr. WYNGAARDEN. Yes, sir; that is established and functioning. It has met already. It has another meeting coming up in the next month or two.

Dr. WATSON. Yes.

In June, we are going to have a plan approved by these advisers—in fact, they are drawing it up now—for how to ask for applications for these centers.

Senator HARKIN. So, basically, what I hear you saying is you really can move ahead fairly aggressively in this whole area right now.

Dr. WATSON. Yes.

Senator HARKIN. You have the researchers out there, the people who can do this?

Dr. WATSON. Yes.

I can't really say where they are, because the applications have not come in. I wish I could say we were going to have a big application from the State of Iowa, but I know we are going to have a big one from a State right next to you. [General laughter.]

HUMAN GENOME INITIATIVE

Senator HARKIN. My understanding, again, just from my layman's reading on this, is one of the reasons it would have been difficult to have conducted this kind of mapping before was the limit on computer ability, and right now you have that ability to do this.

Dr. WATSON. Yes; this whole program would be impossible without computers. We have to train people, many of whom were trained initially as kids with computers, now to learn the biology, to get the information out of the sequences, and how to manage the data. We have to train a large number of people.

I would expect the program to be carried out by people who are now in their late twenties and who we can imagine doing this work over the next 10 to 15 years.

Senator HARKIN. Again, I am not a scientist, not a doctor. But from all the reading that I have done on this, not only on this committee but even prior to my serving on this committee, it leads me to believe this might just be the single, most important, medical and scientific endeavor that we have had at least in the last century.

Dr. WATSON. I think it is the greatest. You know, it is quite unbelievable to me, that after we found the structure of DNA 36 years ago, we could have moved so fast, that we actually could have the genetic message of human beings within a few years.

Senator HARKIN. Well, I am hopeful that this committee will fully fund it, and as long as I am here, I intend to move as aggressively as possible to make sure that this research project is funded and moved ahead very aggressively.

Dr. WATSON. Thank you very much.

Dr. WYNGAARDEN. Mr. Chairman, may I add one point. You alluded to the computer use, and I perhaps should have mentioned earlier that, thanks to the efforts of Senator Chiles and also Senator Pepper in the House, a National Biotechnology Information Center has been established at the National Library of Medicine. That center has a very large role in the organization and management of the information of the Human Genome Project, making certain that it is maximally available to all scientists.

Senator HARKIN. Dr. Wyngaarden, Dr. Watson, or anyone else, any further information that you can give me in terms that I can

understand, as a layman, to help enhance this program, I encourage you to get me that information.

Dr. WYNGAARDEN. Thank you. We will do that.

Senator HARKIN. Let me just ask you publicly, do you share with me this concept, this feeling that I have, that this could be just one of the greatest things that we could do?

Dr. WYNGAARDEN. We are going forward with that same feeling. We can't be all that precise about just what sort of mysteries will be uncovered. We anticipate that we will learn an enormous amount that will provide new insights into diagnosis, management, and prevention of human disease.

Senator HARKIN. We are always going to hear the argument that we are altering life forms and we are messing with the basic structure of life and that we shouldn't be doing that.

How do you answer that question, Dr. Watson?

Dr. WATSON. If we could perform gene therapy to improve the quality of a sick person's life, I would be all in favor of it. I would find it rather immoral not to want to make a sick person well.

Senator HARKIN. Very good. I guess the argument is how do you protect against doing things other than that, though?

Dr. WATSON. I don't really know how to do anything bad now. I know how to do a lot of good things. You can envision some scenarios about how you could do bad things, but they are not as precise as the scenarios we envision to go after Alzheimer's disease, for instance. I like our more precise scenarios.

We do realize that the public is concerned about this issue. We are going to have a strong ethics component in our program. Tentatively we want to spend about 3 percent of our funds in encouraging people to learn what DNA is, to learn what genetic diseases are, to learn what gene therapy really is, and to get as wide a group of people as possible to discuss the matter.

I think we would be making a great mistake if we did not have a strong ethics program.

Senator HARKIN. Well, let's move ahead on that.

I want to talk now a little bit about procurement and scientific fraud.

SCIENTIFIC INTEGRITY

The 1990 budget proposes the establishment of a six person scientific integrity office within the Office of the Director to respond to the increasing allegations of scientific fraud.

An office of scientific integrity review is to be established in the Office of the Assistant Secretary for Health.

As I understand it, the system would still require grant receiving institutions to essentially police themselves. But the institutions would initiate and conduct investigations of fraud at their own institutions and report to NIH. NIH would then review the case and recommend additional corrective actions if it seems necessary.

Basically, this system is almost identical to the guidelines which have been in place for 2 years, and leave all the investigative action with the universities.

The question is when will the regulation be final requiring grant agency institutions to have scientific investigative protocols in place as a condition for receiving an NIH grant?

Dr. WYNGAARDEN. There are several components to the plan and to the points that you have made.

Taking the first one first, we published some time ago, a notice of proposed rulemaking, and it is nearly final now. I think Dr. Raub can tell us exactly where that rests.

That would establish the criteria for the requirement of procedures at the institutional level.

Many schools have those, and many others are in the process of developing them. This would make it necessary for them to have these in place and provide the assurance that they are in place for us to proceed with funding.

In addition, we have a timetable attached to the response concerning events. If the institution finds that there is substance to some charge that has been made there, we expect them to keep us informed of progress. There is a period of time during which we expect that the initial phase of review at the institution will take place. We then expect a report to decide whether the situation has been settled or requires some action on our part.

That has been one point that has been a bit lax up until now. This initial phase at the university has sometimes been handled expeditiously and sometimes it has gone on for months and months. Until they reach a decision, we have often stepped back and let the process evolve. At times, it is clear in retrospect that too much time has gone by.

Therefore, we are establishing closer schedules for the handling of such events.

With respect to our own mechanism, the Office of Scientific Integrity proposal, our plan now is to staff that with eight people. It has evolved somewhat since our initial submission. A major difference is it would be a larger office, it would be higher in the organizational structure at NIH, and it would change the role of the NIH Director and of the Director's Office.

Up until now, the Director has been the deciding official and, therefore was not part of the process.

With this proposal, the adjudicative portion of the process would be moved to the Assistant Secretary level, and we would have the investigative responsibility. The Director could then play a major part in that.

The office in the Director's Office would also encompass the intramural program, which, up until now, has been handled separately, and would also, in effect, be an office for all Public Health Service agencies. It would be jointly staffed for now by the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration. But, should CDC or other agencies have need of it, we are planning to be available for those as well.

In addition to these measures, we have, through the Extramural Grants Office, plans for greatly increasing the educational and institutional liaison activities. We have, regrettably, had considerable experience with these problems now. We can serve as a source of good advice concerning not only the procedures, but the manner in

which the whole issue of scientific integrity can be given a much higher priority in the training of young people entering science.

We intend to do that.

Dr. Raub might answer the specific first question you asked.

SCIENTIFIC INTEGRITY

Dr. RAUB. The only thing I can add, Mr. Chairman, is that the rule is now under consideration within the Office of Management and Budget, having been sent there some weeks ago by the Department of Health and Human Services.

It is my understanding that within a very short period of time, perhaps even a week or so, we will hear from the OMB with a generally supportive view, but probably with some specific further suggestions about the detail of the rule, based on their review and further consultations that they have had with the university community and with others.

It is a major priority to make that rule official as quickly as we can, certainly by summer, and, with any luck, perhaps within this month.

Senator HARKIN. Before I recognize Senator Bumpers, let me just finish up my set of questions.

Senator BUMPERS. Go ahead, Mr. Chairman. I am still looking over this 40 page memo my aide gave me. [Laughter.]

Senator HARKIN. Who has a doctorate, no doubt, in medical sciences, and wrote it in pure English for you, of course.

Senator BUMPERS. Oh, yes. [Laughter.]

PROCUREMENT

Senator HARKIN. On procurement problems, last year, as you know, the committee reduced the budget by $6.7 million and specified to capture the savings that the inspector general reported were available if we had procurement reforms.

In an April 15, 1988, letter, the inspector general noted that $26 million in precious research funds were being lost each year due to inefficiency and mismanagement in procurement.

This year, on February 16, I asked the inspector general to reexamine the situation and tell me what could be saved based on your proposed improvements.

His letter, which I have here, is dated April 26.

He suggests that $13.6 to $21.2 million could be saved annually. So these estimates are a little bit higher than yours.

Could you describe to the committee the status of procurement reform actions and how much savings we might expect from that?

Dr. WYNGAARDEN. Mr. Chairman, with your permission, I would like to make some introductory general comments and then call on Mr. Mahoney.

The inspector general's estimates have ranged from $26 million, later $30 million, and now they are down to $13 to $21 million. In our view, all of these are fanciful estimates.

The most savings we can estimate by examining our processes would be in the range of $6 to $9 million eventually. Some of the items in the inspector general's estimates include such things as public utilities, electricity and water, and so on. It is now clear that

this is not an attainable goal, to secure special rates for the NIH on those.

In spite of that, the estimated savings have not been deleted from the Inspector General's Office. They have just been transferred to some other place where economies are presumed.

The telephone charges are included in that figure, which probably can be negotiated. That is really not part of this procurement issue at all.

We have made progress, as Mr. Mahoney can detail, at securing better——

Senator HARKIN. Can I ask you to back up for a moment. We are having a little discussion here on the telephone deal. Why don't you consider that part of procurement? I mean, you are procuring services.

Dr. WYNGAARDEN. It is procurement, but it is not part of procurement reform. Those are not the kinds of things that were found fault with in our procedures up until now. In a general sense, it is procurement. But those things which are part of our corrective action plan certainly do not center on telephone charges. That is a government-wide issue. In fact, I don't believe we negotiate it.

Do we, Mr. Mahoney?

Mr. MAHONEY. Actually, we have received over the last year a delegation of authority from the General Services Administration to enter into a contract through a competitive solicitation for our telephone system.

We are in the process of evaluating bids at this point and an award will be made some time in 1990.

Our issue with the inspector general on the telephones, as Dr. Wyngaarden said, is one of scorekeeping, not on the fact of whether or not savings can be achieved through a competitive solicitation.

As Dr. Wyngaarden mentioned, most of the criticisms made by the inspector general centered on our delegated procurement system, which consists of those procurements averaging about $750, which can be made directly by ordering clerks.

Our telephone system costs run about $7 million and the contract is negotiated by professional contract negotiators. While we agree that those savings are attainable and we are aggressively pursuing them, it is not as a result of any action that we have taken to reform the small purchase system at NIH.

If I may, I will give you the status that you asked for after the original inspector general's report. We have moved aggressively to develop a comprehensive program that addresses all of the criticisms that the inspector general made.

Basically, one of those criticisms involved the placing of individual orders. We weren't using the leverage that we could have by virtue of the volume of the small purchases that we make, that is purchases of chemicals, administrative supplies, and so on.

The second criticism that the inspector general made was that we had too many ordering clerks and too many ordering points. In effect, the system was too decentralized.

Senator HARKIN. How many was it? I had heard 800-some.

Mr. MAHONEY. We have about 800 ordering and approving officials, not all of whom work full time on the ordering process. About 200 of these people can obligate the Government to a purchase. Again, that is one of the criticisms that was made, not only that we should have fewer people, but that they should be professional people who spend full time on these activities.

With regard to the first of the criticisms, not getting the proper discounts, I should mention that what we are talking about here is not the purchase of $750 hammers. In certain instances, we may have been receiving a 5-percent discount, and should have been receiving a 10-percent or a 15-percent discount.

We immediately began to renegotiate the purchasing agreements that we have with our vendors. We concentrated on those vendors with whom we spend $200,000 or more annually. We have negotiated roughly half of those at this point, and have gathered about an 8-percent additional increase in the discount rate over and above the 5 percent that we had previously been getting.

We have committed ourselves to finishing the negotiations of those high volume vendors by the end of this fiscal year.

We are also experimenting with a competitive solicitation. This is a unique solicitation within the Federal Government, in which we would, in effect, ask our suppliers to compete their entire catalogue for like products against one another. We are confident this would allow us to make additional savings.

Senator HARKIN. You do have the inspector general's report?

Mr. MAHONEY. I do have the inspector general's report.

Senator HARKIN. In his letter to me, he said that NIH believes that only 8 percent to 13 percent savings can be achieved.

That is just what you told me.

Mr. MAHONEY. Yes, sir.

Senator HARKIN. He says, "Whereas we determined, based on NIH's actual experience to date that the percentage range is more realistically 13 to 20 percent." So, 13 percent is the low end for them, and not the high end, as you say.

Mr. MAHONEY. That's correct.

Senator HARKIN. Well, are they wrong, or what?

Mr. MAHONEY. I would say that at this point we have a difference of opinion.

Senator HARKIN. Well, again, what has been your experience to date?

Mr. MAHONEY. Our experience to date is we have averaged an 8 percent increase over and above the 5 percent we had been receiving.

Senator HARKIN. But they claim it is more than that, though.

Mr MAHONEY. They make two qualifications, Senator Harkin.

Remember that I said that we'd been getting a 5-percent discount, and we're now getting 8 percent above the original 5 percent. They found a vendor where we were not getting that 5-percent discount that had been negotiated, and have speculated that that may have occurred more often. They have increased their estimates based on that assumption.

Second, they also have pointed out that, while we average an 8-percent discount, in some specific cases we have gotten a 20-percent discount. That is offset by others where we've gotten less than a 20-percent discount, but the inspector general projects on the basis of these inividual cases, rather than the average, that we may be able to do better than the 8 percent to 13 percent we estimate.

Time will tell which of us is correct and whether it is $6 million to $9 million of savings, as we are saying, or $13 million to $21 million, as they are saying. In both cases, we all agree that those are annual estimates based upon the completion of our long-term program.

It will probably take about 3 years before the program is fully completed.

The second thing that we agree on is our estimates for 1990. The savings will be from $3 million to $5 million.

PROCUREMENT

Senator HARKIN. Let me ask you this.

Are you the person, the administrative person, in charge of procurement reform?

Mr. MAHONEY. Yes, sir.

Senator HARKIN. You are that person?

Mr. MAHONEY. Yes, sir.

Senator HARKIN. And you report directly to the Director?

Mr. MAHONEY. Yes, sir.

Senator HARKIN. How long have you been with NIH?

Mr. MAHONEY. I have been here almost 3 years. I have had charge of this program for about 1 year. It was transferred to me.

Senator HARKIN. What other responsibilities do you have?

Mr. MAHONEY. Mainly budget, personnel, and contracts.

Senator HARKIN. You have under you one person specifically designated to look for savings, to recommend areas in which we might do competitive bidding?

Mr. MAHONEY. Yes, sir; I do.

Senator HARKIN. You have one person just specifically for that purpose. How long has that person been specifically there?

Mr. MAHONEY. A bit less than 1 year.

Senator HARKIN. A bit less than 1 year.

You know, you won't find a stronger supporter of NIH than I am. But, as I get into these budgets in all these areas that I support—labor, health, human services, education—the more I am convinced that there can be in some cases significant and in some cases incremental savings through things like competitive bidding, by just paying more attention to how this money flows out.

The telephones are one thing. They have outlined that here, which should be something looked at. There are many other areas, with 800-some people being qualified to purchase, which raises all kinds of questions.

I am just thinking that if I scaled that down to my own staff size, I might have probably six, seven, or eight people on my staff that could sign checks out of disbursing. Why I'd be in a mess if I had that.

I have one person that can do that. I am just wondering about the scaling of it at NIH. It just seems to me that you have a lot of people who are able to write checks, so to speak.

One of the things I have heard is that a scientist says well, I need some equipment. So they go to whosoever's office they go to and say we need it now, and so they go out and they get it now.

I am wondering if that isn't kind of pushing the system a little bit and whether or not there ought to be a little bit better planning in letting people know that if they want something, they had better think about what they want a little bit beforehand so that we can put out competitive bids and maybe bring in a number of these items that people want, so that we can order in quantity, rather than ordering singly.

I just have a lot of concerns about this area.

Mr. MAHONEY. We agree, Senator Harkin, with everything you have said.

Senator HARKIN. Excuse me for interrupting, but 3 years seems a little long. It seems to me that this is something you might want to get a handle on right away.

Mr. MAHONEY. I think we have started rather quickly. We do have over 1,000 vendors with whom we have to negotiate. With regard to the number of ordering clerks, we have put together minimal workload criteria, and have provided that to the Institutes and asked each of them to develop reorganization proposals.

Those reorganization proposals are in the process of being analyzed. This should significantly reduce the number of people involved in the procurement process.

PROCUREMENT

Senator HARKIN. You might ask yourself and the Director, have we reached the point of diminishing returns on the number of people that you have assigned to this. I don't know how many people you have assigned. When I asked you, you said that you had one person specifically looking at this.

But can that one person handle it all?

My question is can we get more saving through this process if perhaps you have two or three additional people looking at this, rather than just one person?

Do you understand what I'm saying?

Mr. MAHONEY. I do, Senator.

As far as the one person, I have one person who reports to me. There is a group of about 15 or so people who actually monitor all of these activities.

I think the staffing levels for the oversight of this process are probably sufficient. What is necessary, though, is to finish the negotiations of these contracts and to implement the reorganization proposals that the Institutes now have underway.

Dr. WYNGAARDEN. Senator Harkin, if I could add a word or two, we agree with all of the points you have made. The system can be tightened up, and we are working at that. We have a corrective action plan that has a schedule attached to it. We are on schedule with it.

At the inspector general's urging, we have advanced that schedule, and we are moving more quickly than we thought initially we could.

We would like to go back and set the stage for the current problem. If I can have just a minute or two, I will do that.

About 10 years ago, the intramural scientists were very, very unhappy over procurement. There were huge delays and many errors.

My predecessor, Dr. Fredrickson, set up a new office to handle a number of things, and procurement was one. The director of that office made the system responsive.

Our intramural scientists are not reluctant to complain. During the first 5 or 6 years that I was at NIH, I never heard a complaint about procurement from the scientists. They got what they needed, they got it quickly, they did not have to interrupt or delay experiments. They got the precise reagent they needed for that precise experiment.

That was because the system was organized in favor of responsiveness.

Now, in the process, using continuity of research as an argument for not getting competitive bidding perhaps may have been pushed too far. We now find we can do better by negotiating discounts on lot purchases and so on.

Already, with the tightening that we have effected, our scientists are very upset. We have had meetings with some of our best young scientists, and they say, if this continues, they are not going to stay at NIH. That is serious.

All of the regulations on procurement have to do with fiduciary responsibility and procedures. They do not say anything about responsiveness for the mission of the Institutes. Somehow, we have to find a balance in order to meet our legal responsibilities on procurement while still making that system responsive for the scientists. That is our fundamental mission and it is, right now, a little shaky.

Senator HARKIN. Well, I appreciate that.

Still, there must be some way of being responsive to the scientists. But they also have to understand.

Dr. WYNGAARDEN. We are working with them. We hope they understand that better now than they did a month or two ago.

Senator HARKIN. Keep me informed on this as we go along. Any problems that you have on this I would like to know about.

But I just have this nagging feeling, having done this in a couple or three other areas, I have the nagging feeling that there are suppliers out there who have a pretty good deal going. I think that maybe if they were pressed upon, they might give us a little bit better discount, they might be willing to negotiate things a little bit better than they have in the past.

Mr. MAHONEY. You can be assured of our commitment to find them and to effect those savings, Senator.

Senator HARKIN. I appreciate that.

Senator Bumpers, you have been very patient.

PROCUREMENT

Senator BUMPERS. Thank you, Mr. Chairman.

Just to pursue the procurement problem, Dr. Wyngaarden, what percentage of the procurement is for off-the-shelf items that are ready available? Any of it?

Dr. WYNGAARDEN. May I ask Mr. Mahoney to respond to that?

Senator BUMPERS. Sure.

Mr. MAHONEY. That are readily available? I don't have that precise figure, but I would be happy to answer that question for the record.

[The information follows:]

PROCUREMENT SYSTEM

The NIH procurement system is designed to provide quality research products to meet the needs of its scientists. To that end, NIH has established a stocking system to supply common-use items of both an administrative and scientific nature. Our supply system represents a highly successful and cost-effective approach to consolidating requirements, where appropriate. The stock system includes over 1,700 items worth approximately $25 million annually.

NIH has now embarked on a larger consolidation effort. The DELPRO system uses Blanket Purchase Agreements with over 1,200 vendors to obtain supplies, services and equipment, which are typically off-the-shelf and readily available. To evaluate the extent to which further consolidation may be possible, purchases are analyzed to determine the extent items are repetitively purchased. The goal is to identify items that potentially may be purchased centrally and placed into the stock system. A detailed algorithm has been developed to determine whether items recommended for stock can be accomplished at a cost-effective level. Whether or not the items identified for consolidation are stocked, the most cost-effective method of purchase will be determined. This methodology will factor in various administrative costs associated with different purchasing mechanisms.

BULK PURCHASES

Mr. MAHONEY. We do maintain a warehouse, Senator Bumpers, for those items that are commonly bought and available in bulk.

What I had been discussing with Senator Harkin was those items that we do not procure in sufficient quantity to justify stocking them in the warehouse.

I might add that, as part of the corrective action plan, we have developed a new model with which we will be able to identify those items that are bought repetitively so that we can buy them in bulk and stock them in our warehouse and have them readily available, rather than going through the more expensive individual procurement actions.

Senator BUMPERS. Do you find that a lot of the things you procure at NIH are only manufactured or available from one source?

Mr. MAHONEY. There is a fair amount of that, Senator Bumpers, and, in addition, there are subtle differences of purity in chemicals between manufacturers. Even though there may be two chemicals manufactured, because of these subtle differences in the purity, there really may be only one supplier.

Senator BUMPERS. How about scientific equipment? Let's say one of your researchers says I need a gadget that will do so and so, and such and such, and, so far as I know, there is not one available anywhere. How would you go about finding somebody to manufacture or to make that thing on a one-time basis for you?

Is there some kind of review process that you would go through before you would order a device like that?

Mr. MAHONEY. Actually, we have a very fine facility at NIH for that sort of situation.

Senator BUMPERS. Where you do a lot of manufacturing of special devices?

Mr. MAHONEY. We do most of that right at NIH.

NIH DIRECTOR

Senator BUMPERS. Dr. Wyngaarden, how much longer are you going to be with us?

Dr. WYNGAARDEN. Well, through the morning. [Laughter.]

Senator BUMPERS. When do we get a shot at your successor?

Dr. WYNGAARDEN. I will be here till about the first of August.

Senator BUMPERS. In that connection, who will make a recommendation to the President for your successor?

Dr. WYNGAARDEN. Yes.

The President has agreed that there will be a national search. There will be a search committee chaired by the Assistant Secretary of Health, who was just confirmed last week, Dr. James Mason. He has consulted with us about the structure of the search committee that he plans. I am pleased that it will be a broad search committee, quite a large one, with Federal representation and also outside representation, including excellent scientists and managers. They will do what we normally do in such situations; that is, contact the extramural community, the deans of medical schools, public health schools, nursing schools, the major professional societies, the Academy of Medicine, the National Academy of Sciences, and on and on. That will, no doubt, lead to many nominations.

Then the committee will sift through and rank these, and interview some. Dr. Mason has been asked to submit three names to the President by way of the Secretary. Then the final choice will be made.

Senator BUMPERS. They don't have to pass the "James Watt test," do they? They don't have to be conservative Republicans in order to get on the list.

Dr. WYNGAARDEN. Not to get on the list; no. [Laughter.]

Senator BUMPERS. You know, one of the reasons the Soviets were so far behind at the beginning of World War II is because there was a guy who was Stalin's scientific adviser who told him that all scientists had to be ideologically pure as well as scientifically good.

So, unhappily, a lot of the good scientists had either been executed or shunted aside, and the Soviets were really way behind.

When Ronald Reagan came to town in 1981, of course, he adopted a policy of ideological purity before anybody could be nominated.

I can tell you that Senator Harkin and I will be watching very closely to make sure that we find somebody who measures up professionally, I don't care what his political affiliation, philosophy, or anything else is.

But I don't mind telling you that I am always troubled by that because I know politics. I know how it works.

While the head of NIH, who has to come up here and testify before these committees, has to be savvy enough to defend the budget, he also has to be professional and scientifically pure enough to tell this committee the truth about what you really need and not just what OMB tells you you need.

RESEARCH PROJECT GRANTS

This gets me to my very basic first question.

The number of new and competing grants has now declined from about 5,850 in 1988, to 4,456 in the 1990 budget request.

Now, noncompeting grants are holding fairly steady. But my question is this. Are there very meritorious applications that you wish you could fund but simply do not have the money?

Dr. WYNGAARDEN. Yes, sir; that is certainly the case.

The Institute Directors and I estimate that the historic average of 45 percent to 50 percent is still a goal that we should strive toward if funds would permit that. There is a lot of good research that we are unable to fund. It does drop off in quality eventually and even some of the projects that are approved are approved at a relatively low priority.

Our priority is for the award rate to increase to 45 or 50 percent of the approved applications.

Senator BUMPERS. In the current year 1989, or, if you don't have statistics, go back to 1988, what would it have cost to have funded that level of grants, new grants?

Dr. WYNGAARDEN. For 1990, to fund approximately 45 percent, including AIDS, of the approved applications would require about $800 million.

Senator BUMPERS. So, at least ideally, you would have needed another $800 million to meet the criteria that I just pointed out.

Is that correct?

Dr. WYNGAARDEN. Yes; it is on that order for 1990.

Senator BUMPERS. Do you remember the Weicker language that required NIH to come up with 6,200 new grants a year?

Dr. WYNGAARDEN. Yes.

Senator BUMPERS. As much as I liked Senator Weicker, I never did think that an arbitrary number like that was very appropriate. But laymen, like Senator Harkin and I and other members of this committee, have to depend on your professional judgment, and I am willing to do that. That is the reason it is so important that the head of the NIH and the head of the Institutes are totally candid with us at all times.

AIDS BUDGET

Perhaps the next question ought to go to Dr. Fauci.

Is the fiscal year 1990 request for AIDS research enough? I promise that you won't lose your job if you say no.

Dr. FAUCI. We have asked for more than is in the President's budget. When we get our scientists together from the different institutes and ask them to make a proposal for what they think can be reasonably spent, we go over it, first in the Office of AIDS Research, for gross duplication, overlap, relevancy, and then Dr. Wyn-

gaarden and I sit down and go over it again to make sure that it is as good and sound a budget as possible.

That budget that Dr. Wyngaarden and I decided upon was a higher budget than what appears in the President's budget. So, if by definition that means that there is not enough, then there is not enough. But there are a lot of things going on that are sound, good science.

We are proud of what we are doing, but the actual amount that we asked for is not what came back from OMB.

Senator BUMPERS. Well, then, I can conclude from what you said, Dr. Fauci, that under a current services budget, your 1990 request is not sufficient, is it?

Dr. FAUCI. That's correct, Senator.

Senator BUMPERS. How much would it take to make it sufficient?

Dr. WYNGAARDEN. Are you asking about the AIDS budget now?

Senator BUMPERS. Yes.

Dr. FAUCI. The amount that we requested of the Public Health Service was $990.2 million. The President's budget request for 1990 is $752,670,000.

We had asked for approximately a 50-percent increase over 1989, and we got about a 25- to 28-percent increase.

Senator BUMPERS. So, we are $237 million off the mark?

Dr. FAUCI. Approximately.

Senator BUMPERS. Well, I think there is a distinct possibility, Dr. Fauci, that, based on what you have just said, we can up that. I am not sure that we can get you up to the full $900 million, but I certainly think we can do better than the 1990 request.

NONAIDS INCREASES

In that connection, let me pursue just a little bit further, since I am questioning you right now, the non-AIDS part of your Institute.

I guess the best way to approach this is to read you a little bit of a letter which I found interesting from a doctor at M.D. Anderson. I won't read you the whole thing, but he says, "I am writing to express my serious concern about the projected drastic and, in my opinion, unwise cuts in the non-AIDS portion of the budget for NIAID in 1989 and the proposed further cuts in 1990. Non-AIDS research project grants funded by NIAID"—how do you all say that? What is the acronym for that?

Dr. FAUCI. It's NIAID.

Senator BUMPERS. Thank you—"will decline." I am a new boy on the block, so I have to get used to all of these acronyms. It "will decline by 12.9 percent in 1989, and the President's budget calls for an additional 25.7-percent cut in 1990."

Then, I guess the core of it is this. He says, "Let me cite two important examples. In the early 1970's, many research projects were directed at determining if viruses, especially a special class of viruses, called retrovirus, was the cause of human cancer. It became clear in the mid- and late-1970's that, while some forms of human leukemia were associated with these viruses, not all forms of cancer were caused by viruses. So interest in the subject abated."

He goes on: "But a few laboratories in the world continued to study the basic biology and biochemistry of these viruses, not be-

cause they were the cause of cancer, but because their biological properties were so unique. In the early 1980's, it was discovered that a retrovirus did, indeed, cause AIDS. Because a few laboratories had continued to study the biology of these viruses, they were in a position to spearhead the drive to develop a simple and reliable test for the AIDS virus."

How would you respond to that, Doctor?

For the record, this is a letter from Dr. S.E. Ulrich, Assistant Professor of Immunology, M.D. Anderson.

Dr. FAUCI. The concepts that are put forth in that letter are correct. The numbers of reductions are a little bit off, but I can explain that.

I think the whole idea of having AIDS funding grow is appropriate, because this is a very serious problem and the No. 1 public health problem of the Public Health Service. But it is critical, as I have said many times, that we do not allow the non-AIDS part of the NIH budget to suffer to the point of not growing commensurate with the scientific opportunities.

There have not been cuts, strictly speaking, in non-AIDS. But if the growth in AIDS, be it money or be it FTE's, leads to a lack of appropriate growth in non-AIDS, I think that is a big problem.

The point that is made in that letter is true.

Years ago, in the war on cancer, a lot of money was put into cancer and a lot of very positive spinoffs that transcended cancer occurred. One of them is the work done by Dr. Gallo and his colleagues and others at the NIH and elsewhere on retrovirology.

I think you are going to see the same thing in the basic research base of my institute and the other institutes. But if you neglect basic biomedical research, as alluded to in that letter, not only is that a problem right now for the other disciplines, it might have a negative impact on diseases that we don't even know anything about right now.

So we are greatly concerned, myself and the other institute directors, and Dr. Wyngaarden, about making sure that basic biomedical research grows at a rate commensurate with the extraordinary scientific opportunities that we face.

NON-AIDS BUDGET

Dr. WYNGAARDEN. Senator Bumpers, I can give you some of the figures for the non-AIDS portion of the budget.

You asked about the current service budget and I gave you 1989 figures. For 1990, including AIDS, the figure would be $8.085 billion.

Senator BUMPERS. That's $8.085 billion?

Dr. WYNGAARDEN. Yes; that is the current service budget. It would fund only 5,324 new and competing awards because that is what is in the 1989 budget. To fund 6,200 awards, it would cost an additional $350 million over that current service figure for that part alone. That still assumes some considerable downward negotiation.

The request that came to me from the institute directors initially for non-AIDS funding for 1990 was $9.5 billion. We eliminated some overlaps and made some judgment calls, and sent the request

for $9.177 billion to the Public Health Service. They requested $8 billion of the Department. The Department requested $6.975 billion of OMB, and the President's request is $6.776 billion, for non-AIDS.

RESEARCH FUNDING

Senator BUMPERS. Dr. Wyngaarden, how do we compare with countries like Germany, France, and Japan in spending for health research?

Dr. WYNGAARDEN. In terms of fraction of the respective gross national products?

Senator BUMPERS. I know that that is a tough comparison, but just give me a general idea.

Dr. WYNGAARDEN. We are somewhat lower than most of those and lower than Japan.

If one looks at the Common Market countries of Western Europe collectively, their expenditures for biomedical research are very close to ours.

I don't have those precise figures. The population base there is perhaps 10 percent larger than ours, about 275 million.

Senator BUMPERS. Then the number of dollars would be comparable, about the same?

Dr. WYNGAARDEN. I am told that they are essentially comparable to ours.

Senator BUMPERS. How much coordination is there between NIH and your counterparts in other countries?

Dr. WYNGAARDEN. We are invited guests at the annual meeting of the European Biomedical Research Council. We meet with them and hear about the major thrust of the research there.

Senator BUMPERS. Is anybody doing as much AIDS research as we are?

Dr. WYNGAARDEN. No; we conduct the most AIDS research.

I think Dr. Fauci could perhaps give you a better estimate. There is some good work going on in Europe, some very good work, at the Institut Pasteur and various laboratories on the continent and in England. But it doesn't approach the investment that we have made in AIDS research. It's not even close.

CLINICAL TRIALS AND DRUG DEVELOPMENT

Senator BUMPERS. Dr. Wyngaarden or Dr. Fauci, either one of you, when you have a chemical, for example, we'll take whatever the chemical being developed from the Chinese cucumber root is, and you decide to go to tests, to human trials, clinical trials, on that, are you free to make that judgment yourself, or does FDA have any part of that decision at that stage of the game?

Go ahead, Dr. Fauci.

Dr. FAUCI. What usually happens is that a drug, like the drug in question, is used in a test tube to see if it can block AIDS virus replication or kill AIDS infected cells. That does not require any permission or go-ahead from the FDA.

Once you want to test something in humans, it requires an investigational new drug application, an IND, for a phase I trial, which is an early trial looking at safety. The first thing is safety and setting the correct dosage.

Senator BUMPERS. Do you have to do that for animals other than man?

Dr. FAUCI. We don't have to do it for animals, but when you want to use it on humans, you need an IND from the FDA.

That is not a difficult thing to do, to get a phase I IND for a drug, like the Chinese root drug to which you alluded. In fact, the company itself has already applied and has either already gotten or will soon get an IND to go ahead with human trials.

So, it is relatively easy, if you make a judgment that a drug has some scientific merit and some indication that it might be safe and effective in humans, to go ahead and do that phase I trial. That is not the problem, to get that early trial.

The quickness with which you move further is obviously debatable in a number of areas. But getting that first phase I trial is not a problem.

Senator BUMPERS. How do you assess or would you assess the potential for this new drug?

Dr. FAUCI. At this point in time, it would be very difficult to make any sound, scientific statement about that. There are a large number of drugs that can block the AIDS virus in a test tube. The really critical issue is, will a drug be able to be used in a way that is safe at the same time that it can accomplish the underlying goal of what you are trying to do, which is to suppress the AIDS virus.

There are a number of compounds that we have heard about and several that we have tested that have good activity in the test tube. Then, when you finally make the step to try the drug in humans, you may see that either it isn't absorbed in the body, it isn't active in the body, it gets deactivated, it is too toxic, et cetera.

So there is a rather large leap from the test tube to a human study, and as always, more drugs will have activity in the test tube than will be able to be used in a trial with humans.

Senator BUMPERS. If that is true, why is this drug receiving such an acclaim?

Dr. FAUCI. Welcome to the world of AIDS publicity.

Senator BUMPERS. I see.

What is the protocol that Jenny is on? What is that drug? She's the little girl from Michigan that I spent some time with out there.

Dr. FAUCI. Well, Dr. Broder might know.

Dr. BRODER. If I could answer that, the drug is dideoxyinosine. The abbreviation is ddI.

Senator BUMPERS. Was that a drug that was selectively destroying the AIDS virus in the test tube?

Dr. BRODER. Sir, ddI was developed in collaborative activity between the Cancer Institute and the National Institute of Allergy and Infectious Diseases. It now is in study at the NIH Clinical Center, and it is also being studied at several different research centers. A manufacturing license has been given by the Government to the Bristol Meyers Corp. It is a Government-owned drug, with a licensing arrangement with a private company, as part of the Federal Technology Transfer Act.

Senator BUMPERS. I see.

CLINICAL TRIALS AND DRUG DEVELOPMENT

Dr. FAUCI. There is a combination of screening. At the NIH, predominantly at the Cancer Institute, we have the capability of screening large numbers of compounds that might have some potential activity against the AIDS virus.

There is also what we call a targeted drug development program where you don't rely on random screening of drugs that are already on the shelf or that are submitted to us from outside sources. You actually use the information you have about the structure and function of the virus to target particular drugs that you feel might be effective against the AIDS virus.

The screening and the targeted development are the major sources for drugs like DDI and DDC and other drugs that we are now testing at the NIH and by NIH funded organizations.

Senator HARKIN. Senator Bumpers, if I might, if you would yield, we have all the institutes before us today.

Senator BUMPERS. Mr. Chairman, I'm sorry if I've taken too much time. But I have one additional question.

Senator HARKIN. Oh, that's all right. I just wanted to say that we are going to get to Dr. Fauci's institute and we are going to get to Dr. Broder's institute. We are just going to go down the line here. I have some questions about AIDS, and we will do that at the time.

Senator BUMPERS. I'm sorry if I jumped the gun on that.

Senator HARKIN. That's OK.

Senator BUMPERS. I want to ask Dr. Wyngaarden about something that really is of great concern to me.

RECRUITMENT AND RETENTION

You told me when I was out there that you had lost 28 percent of your senior scientists in the last 6 years and have not been able to recruit a single replacement.

As I understand it, you have a fund there—and I forget the name of it—some kind of allowance under which a senior scientist, for example, is entitled to a payment in addition to his base salary.

Dr. WYNGAARDEN. Yes; that is correct.

Senator BUMPERS. But, as I understand it, the $20,000 may not be used to take you above the $89,000, is that correct?

Dr. WYNGAARDEN. That's correct. Yes, sir.

Senator, I'm sorry. The figure is $99,000.

Senator BUMPERS. Oh, is it $99,000?

Dr. WYNGAARDEN. Yes, $99,000.

Senator BUMPERS. Well, still, when you consider the chairmen of clinical sciences departments in medical schools have average salaries of $178,000, $99,000 does not compare favorably.

But what is even more disturbing to me, of course, is this disparity. Obviously, your loss is going to continue. The attrition rate is going to be unacceptable out there.

I want to be sure, as a matter of semantics, that we are talking about the same thing.

Have you been able to recruit replacements from within the Government, have you not been able to recruit anybody, period?

Dr. WYNGAARDEN. The statement is that we have not been able to hire from outside. We have promoted entirely from within.

Senator BUMPERS. Well, have you been able to recruit enough to fill out the losses?

Dr. WYNGAARDEN. Fortunately, we have a very deep bench. We have a marvelous supply of young scientists. But we are finding that, with the growth of the biotechnology industry and the demography of faculty turnover in medical schools, the competition is greatly increased and we are losing more senior scientists than we have in the past. We are having more difficulty holding on to our emerging, bright, young scientists as well.

When I came to the NIH in 1982, the difference between the average salary we paid our SES scientists, medical scientists, and the department chairmen was $35,000. Now it is $99,000. That is the way the gap has grown in a period of 7 years.

Senator BUMPERS. Mr. Chairman, just in closing, the reason I ever wanted to be President of the United States was to establish a whole new set of priorities for this country. When I see us spending the kind of money we are spending on some projects—and I am not just kicking defense or SDI—but when I see that and when I hear this testimony, where they are asking for $7.2 billion and could use up to $9 billion, for the health of this Nation, I am sickened. In my opinion, the good health of the Nation goes a lot more to the strength of the country than how many tanks, planes, and guns we have.

I know that the chairman has said you all waste money, just like we all waste some money. But I cannot think of any higher priority in this country.

Thank you, Mr. Chairman.

Thank you, Dr. Wyngaarden. We wish you well.

Senator HARKIN. Thank you, Senator Bumpers.

I have just one last thing before I leave the issue of procurement.

Would you provide me with the number of individuals that in NIH perform procurement activities, either full or part time, both for this year and what you project for next year?

Mr. MAHONEY. We would be glad to, Senator.

[The information follows:]

PROCUREMENT

DELPRO

The Logistics Management Institute had indicated in its report on NIH purchasing practices that over 800 staff at NIH were delegated authority to place small dollar orders. This large number of staff has often been used as the basis for statements that NIH's DELPRO (delegated procurement) system is unwieldy and prone to inefficiencies.

The figure cited by the Logistics Management Institute needs to be carefully interpreted, however, since this has often led to the conclusion that over 800 people were authorized to obligate the Federal Government. In fiscal year 1988, of the approximately 825 people involved in DELPRO purchasing activities, 200 could approve orders. These approving officials, as they are called, are responsible for ensuring regulatory compliance and obligating the Government. By contrast, ordering officials are only authorized to contact vendors to obtain information on prices, item availability, etc., and to place the order verbally after authorization by the approving official.

As part of its procurement reform, NIH conducted a study in early 1989 of its ordering offices and officials. This survey, which was used as the basis for development of criteria for the Institutes to use in reorganizing their organizational structure for DELPRO purchasing, generated new data on the number of ordering and approving officials. These data indicated that at the beginning of fiscal year 1989

the number of ordering officials had slightly increased to about 634 and the number of approving officials decreased to 147.

We believe that this number is too high and are reducing the number substantially by the reorganization noted above. We project, based on a preliminary analysis of the Institutes' reorganization proposals, that the number of ordering and approving officials will be reduced approximately in half. By focusing procurement responsibilities in a much smaller number of people, NIH believes it will be able to achieve the objectives of cost economy and regulatory compliance in DELPRO purchasing, while maintaining responsiveness to its scientific community.

These reductions in numbers of authorized ordering and approving officials do not necessarily represent reductions in FTE's devoted to procurement activities. Most of the ordering officials are currently carrying out this function on a part-time basis. In our reorganization, we are moving to the concept of full-time ordering officials as recommended by LMI. We will be pleased to provide the Committee the precise numbers of ordering and approving officials and the FTE implications once the reorganization plans are approved by Dr. Wyngaarden in June.

DIVISION OF PROCUREMENT

Through its Division of Procurement, NIH processes centrally its higher dollar, more complex small purchases for equipment and services. The Division also awards contracts in support of NIH's intramural research mission and to support the NIH facilities. Staff in the Division are comprised of full-time, professional contract specialists and purchasing agents, as well as necessary support staff. In fiscal year 1988, the total FTE complement for the Division, including support staff, was 113 positions, although not all of those positions were fully utilized due primarily to the difficulty we experienced in recruiting qualified staff. An additional four positions were added to the Division roles in fiscal year 1989, due to initiation of procurement reforms at NIH. Four more positions were also allocated to staff the newly-established single Principal Official Responsible for Acquisition (PORA) function in another Division of the Office of Administration (i.e., the Division of Contracts and Grants). The establishment of the single PORA function will help ensure the effectiveness, efficiency and integrity of all NIH acquisition activities through the establishment of consistent and appropriate controls.

For fiscal year 1990, we have established a position level of 121 for the Division of Procurement, due to the projected increase in contract activities related to increased AIDS efforts and the accelerated focus on negotiating discount agreements with high volume DELPRO vendors. A major reorganization for the Division of Procurement was also approved recently which will provide better career opportunity for the staff and, over the long term, assist in our efforts to recruit and retain the highest caliber procurement staff. Although only in the planning stages at this point, we are proposing an increase in the position level for the Division of nine additional staff for fiscal year 1991. This increase, if approved, will be used to process the projected increase in AIDS and AAALAC-related projects.

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As part of its procurement reform, NIH has undertaken a study to evaluate the necessity for decentralized offices and to develop appropriate criteria for their establishment.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I have some questions about buildings and facilities, which I will skip over and we will submit those in writing.

Dr. WYNGAARDEN. We will be happy to respond, Senator.

Senator BUMPERS. Mr. Chairman, I may want to submit a few questions for the record, too.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

DIRECTOR'S DISCRETIONARY FUND

Question. The budget proposes the creation of a new $25 million discretionary fund for the Director of NIH in order for the Director to have the flexibility to respond to new scientific opportunities. Why couldn't such opportunities be responded to by simply reprogramming or redirecting activities within the Institutes? What would the process be for awarding grants from this new discretionary fund? Would they be peer reviewed?

Answer. The purpose of the proposed $25.0 million fund is to allow NIH to be more responsive to emerging research opportunities and health priorities without requiring a redirection of funds from other important activities. Amounts will be allocated to NIH components and funding mechanisms as needs become apparent. Had this type of fund been available in FY 1989, it could have provided support for the stipend increase in the research training program without causing such a large reduction in the number of trainees to receive support. Another example of a use for this fund would be to provide matching funds to the BIDs to support the new effort to encourage minority participation in biomedical research through the supplementation of research project grants. As another example, had we had such a fund in 1982 and 1983, the AIDS effort would have been launched more expeditiously without detracting from other pressing program needs.

Reprogramming or redirecting activities within an Institute is one way of dealing with unforeseen requirements within the Institute. However, there is currently no expeditious method of moving funds between Institutes to support needs of one Institute that may be judged to be of higher priority than those of another. This fund would facilitate meeting such needs.

Grants awarded from the new discretionary fund would go through the same process as all other grants, including peer review.

STIPENDS

Question. Last year after the committee completed its action on the budget, NIH took action to increase the stipend for biomedical trainees, the pre-doc stipend was increased from $6500 to $8500 and the post-doc stipend was increased from 5 to 14 percent or from $1000 to $3000. This resulted in a reduction of the number of research training slots that could be funded from the 11,600 anticipated by the committee to 10,300. To fund the level of training slots anticipated by the committee would now cost approximately $25 million.

Dr. Wyngaarden, please tell the committee your logic in increasing the stipend which has eliminated more than 1000 training slots across the country, and where and what institutions will lose training slots as a result of the decision to increase the stipend?

Answer. Before recommending the increase in stipends, the NIH leadership gave this matter careful consideration, fully aware that such an action most likely would result in a reduction in the number of research trainees. Despite increases in the cost of living and a

revision in the tax law, which made stipends taxable, NIH had not proposed a stipend increase since FY 1985. In addition, a review of stipends paid by other government agencies for comparable training awards and of average house staff salaries at U.S. teaching hospitals indicated that NIH stipend levels were among the lowest.

The NIH staff and the extramural scientific community have expressed concern that the training grants due for competitive renewal in FY 1989 would bear most of the burden of the requisite reduction in the number of research trainees. This would affect training programs all over the country. An internal NIH review revealed that, without some special action, some Institutes would have no funds available for competing training grants.

In order to help lessen this unintended consequence, the Institutes have carefully reviewed their research training portfolios and identified unexpended funds, unfilled training positions and other opportunities for savings within existing training grants, as well as examined the programmatic merit of all noncompeting continuation awards. It has also been decided to maintain tuition payments for FY 1989 at the FY 1988 level to generate additional savings. In addition, the NIH has proposed a reprogramming of funds into the research training mechanism. The combination of these measures, if the reprogramming is approved, will enable NIH to support an additional 810 trainees for a total level of 11,116.

We believe the actions taken and planned are appropriate and are in the best interest of the NIH biomedical research and research training programs.

HUMAN GENOME

Question. The largest single increase at NIH is the $72 million for the Human Genome project. While this money is included in the National Institute for General Medical Sciences, I understand that NIH proposes to manage it from the Office of the Director. I understand that an NIH sponsored conference last year suggested that spending for the Human Genome project should be increased each year for 5 years until it is at a level of $200 million per year and be maintained at that level for 15 years for a $3 billion effort. In some quarters the effort has been hailed as the "Manhattan Project of the Life Sciences." I don't believe that accountability is very clear by having the money in one Institute but the active program management out of your office.

Is it accurate to say that you would prefer to have the funding consolidated in a new organizational entity, or a center for the Human Genome?

Answer. Yes, Senator, that is correct. Currently, the management of the funds earmarked for the Human Genome Program at the NIH is the responsibility of the National Institute of General Medical Sciences (NIGMS). The Office of Human Genome Research (OHGR), on the other hand, was established as a staff office within the Office of the Director, NIH to carry out planning, policy development, and intra- and inter-agency coordination functions.

The proposed National Center for Human Genome Research would replace the OHGR, combine the several functions, and would be an independent operating unit, with its own appropriation and its own authority to review and award grants with advice from its own National Advisory Council.

The primary reason for considering such an organizational change at this time is the desire to ensure that the program planning, implementation, and management activities are carried out by a single organization. While these activities have, to date, been successfully coordinated between NIGMS and OHGR, two features of the program warrant their consolidation at this time. These are the proposed rapid expansion of the funds available to support genome research and the significant way in which the organization of the genome program differs from the typical basic biomedical research program administered by the NIH. The genome program will involve a much more highly targeted and directed scientific effort than the investigator-initiated projects that have been the backbone of the basic molecular biology and genetics programs at NIH. The genome program will concentrate on the development of new technology, the production of mapping and DNA sequence data, and the establishment of resources and means for the collection, storage, and distribution of both materials and information. As a separate administrative unit, with the primary mission of achieving the goals that have been set out for the genome effort, the proposed Center will also be dedicated to maintaining a close relationship with the other Institutes, particularly NIGMS. This will help ensure that the resources that are developed under the aegis of the genome program are made available to the wider community of biomedical researchers for use in the study of basic biological phenomena, in the study of the genetic aspects of human disease, and in the development of methods of diagnosing, treating, and preventing such disease.

Question. Last year the Committee urged NIH to establish an advisory panel on the Human Genome. Has that panel been established, and could you tell us of your effort to coordinate Human Genome spending with the Department of Energy, the National Science Foundation, and other Federal agencies?

Answer. To address the intent of the Senate for proper planning and coordination of the Human Genome Project, the NIH has established a Program Advisory Committee on the Human Genome. The charter of the Committee requires it to advise the Secretary, DHHS; the Assistant Secretary for Health; the Director, NIH; and the Associate Director for Human Genome Research on both near- and long-term aspects of the genome program. The Committee represents the broad range of scientific expertise necessary to oversee this project, including the area of ethics. It has twelve members, among whom are members from industry, including small businesses, and academia. Several federal agencies, including the Department of Energy (DOE), the National Science Foundation, and the Department of Agriculture, as well as the Howard Hughes Medical Institute, are represented by liaison members to the Committee.

As specified by the Memorandum of Understanding signed by the NIH and the DOE, a subcommittee of the NIH Program Advisory Committee will meet jointly with a subcommittee of the DOE Health and Environmental Research Advisory Committee to assure that advice to the two agencies is congruent. Members of the NIH Advisory Committee in conjunction with representatives of the DOE and other agencies will also prepare a national plan for the Human Genome Project as the Senate requested of the NIH last year. Finally, to ensure that the recommendations of the several advisory committees are implemented properly, the staffs of the NIH and the DOE meet regularly and exchange information about each agency's progress and plans for spending the funds earmarked for the Human Genome Program.

Question. You have requested two year authority for these funds, while all the rest of NIH has one year spending authority. Does this mean you cannot spend all the money in fiscal year 1990?

Answer. Senator Harkin, I believe that we can spend the funds in one year. However, because the program is so new, and because we are still developing some of our plans, we would like the flexibility of a little extra time, just in case we need it. The state of scientific achievement and potential for progress in genome research warrants the level of funding requested. Several new initiatives are planned for FY 1990. These include the development of a program of Genome Research Centers, the initiation of a Genome Training Program, and an expansion of the ethics research component of the genome effort. In order to ensure that these new aspects of the Human Genome Program are implemented successfully, it is reasonable to allow an appropriate amount of time to investigators to plan their proposals, and to NIH staff for review of the applications and award of the grants. Although planning efforts for most of these new programs have already started within the NIH Program Advisory Committee on the Human Genome and the Office of Human Genome Research, the possibility exists that it will be neither prudent nor responsible to rush to finish making awards by September, 1990, rather than taking an extra month or so, if it seems warranted.

PROCUREMENT

Question. Last year, the Committee reduced the overall NIH budget by approximately $6.7 million to capture the savings that the Inspector General reported were available if NIH would institute recommended procurement reforms. In an April 15, 1988 letter, the Inspector General noted that"...$26 million in precious research funds are being lost each year due to inefficiency and mismanagement."

This year, on February 16, I asked the IG to reexamine the situation and tell us what could be saved based on your proposed improvements. His letter report dated April 26, 1989...just last week...suggests that $13.6 to $21.2 million could be saved annually. These estimates are slightly higher than yours.

Could you describe to the Committee the status of procurement reform actions, and will those efforts result in additional savings in fiscal year 1990?

Answer. At the center of the procurement criticism contained in the Inspector General's report was the Delegated Procurement System (DELPRO) which is a highly decentralized but extremely responsive system for the purchase of small dollar scientific and administrative supplies. Purchasing through this system is usually limited to items less than $5,000 and the average order is about $750. Items above this dollar threshold are purchased through central procurement offices staffed by professional purchasing agents. Purchases through DELPRO in 1988 totalled $107 million (excluding utilities and consolidated purchases through Indefinite Delivery Contract orders) and purchasing in the centralized settings totalled $166 million.

While the total estimate of $26 million in savings projected by the Inspector General was controversial, NIH agreed that it was essential to take all steps necessary to achieve maximum possible savings while maintaining acceptable levels of responsiveness. A 46-point action plan was developed by NIH and approved by the Assistant Secretary for Health in June 1988 and by the Assistant Secretary for Management and Budget in August 1988. The major elements of the plan are summarized as follows:

1. Establish a New Organizational Framework for Procurement and Logistics at NIH

   This included the transfer of the procurement and logistics functions from the Office of Research Services to the Office of Administration; the hiring of a senior acquisitions manager to direct the development and implementation of this plan; the establishment of a Procurement Advisory Group comprised primarily of senior research scientists to assure that actions taken are consistent with NIH's research mission; the establishment of a single Principal Official Responsible for Acquisition to assure an oversight of all acquisitions at NIH including small purchases and Research and Development contracts; and the establishment of performance standards for all responsible officials.

2. Increase the Discounts Above Levels Being Achieved

   A three-part strategy was developed to obtain additional discounts. A novel concept in the purchasing of the small dollar items was developed--a unique competitive solicitation leading to the award of Blanket Purchasing Agreements (i.e., simplified ordering mechanisms). Under this concept, all items purchased through DELPRO would be divided into about 50 generic categories. Vendors would then be asked to compete against each other by guaranteeing across-the-board discounts for all items that they sell in that category. Users would then select a vendor for a requirement based on a preferential source list, which lists vendors in descending order of potential cost savings. Since this is an experimental and lengthy process, we simultaneously entered into one-on-one negotiations with our vendors. With over 1,000 vendors, we initially concentrated on those with whom we do the largest volume of business. Finally, we are increasing the number of ordering agreements with vendors with whom GSA has established guaranteed minimum prices on selected items.

3. Reexamine the Staffing and Organization of Purchasing Activities

A special effort was undertaken to reorganize DELPRO purchasing activities with the goal of reducing the number of personnel that place orders and to assure that ordering staff performs these functions full-time. Standard workload criteria have been established, and organizational proposals have been developed by the Institutes consistent with these criteria.

4. Enhance Central Management and Monitoring Capability

Since purchasing through DELPRO is highly decentralized, it was considered essential to provide strong central management oversight and support. Actions taken include improved data collection to analyze discount potential and to assure that discounts are received; the development of a management information system; the development and provision of a variety of training courses for ordering officials, approving officials, and scientists; the development of a strong monitoring capability in which large samples of actions would be reviewed and follow-up audits conducted when necessary; the provision of tools that detail information for the ordering official on the items on which GSA has negotiated discounts, and the items that are carried in the NIH warehouse; and the development of a mathematical model to determine when it is economical for NIH to stock a particular item in its warehouse.

5. Special Studies

These include studies on the career ladder and grade levels for purchasing agents; an assessment of the adequacy of our internal controls; and the feasibility of further decentralizing purchasing activities.

As noted above, NIH is simultaneously negotiating individually with vendors while developing the unique competitive solicitation. These one-on-one negotiations were undertaken in recognition of the necessity to begin to achieve immediate savings while the long-term solution was being developed. First, priority in these negotiations was placed on those vendors for whom NIH purchases $200,000 or more per year. The Inspector General concurs with this strategy. We are committed to enter into negotiations with all of these vendors by September 30, 1989.

To date, excluding utilities, we have completed negotiations with 25 vendors whose sales exceed $200,000 per year to NIH. This represents negotiations completed with vendors which represent 55 percent of our dollar sales in this category. We also have negotiations underway with vendors whose sales represent another 22 percent. These negotiations have produced agreements to provide additional discounts of 8 percent above the average of 5 percent that our vendors were providing. In other words, the initial round is producing an average discount of 13 percent.

With regard to the competitive solicitation, our pilot solicitation for the office supplies category was awarded in early April. It generated discounts ranging from 25-42 percent among the

17 vendors awarded Blanket Purchasing Agreements. If this solicitation is representative, NIH should be able to increase its savings potential through this mechanism over the current one-on-one negotiation process. An additional four commodity categories are scheduled for competition in June and July.

Because much of the effort to be undertaken is innovative and long-term, the estimates of annual savings upon completion of this project is somewhat speculative. Because of differences in assumptions, NIH and the IG differ on the amount of annual savings potential to be achieved when this project is complete. However, the calculation of anticipated savings likely to be achieved in FY 1990 is relatively straightforward as it is based primarily on the experience of the negotiations completed to date or anticipated to be completed in the short-term. Projecting from the negotiations that have been completed, both NIH and the IG anticipate that the annual savings in FY 1990 will be $3-5 million. This is an increase of $2-4 million above the savings achieved in 1989.

The fact that NIH projects a lower level of savings upon completion of this effort should not be interpreted as a lesser commitment to achieve these savings. In fact NIH has every incentive, and is totally committed, to achieve all possible savings while maintaining an acceptable level of responsiveness to its scientific mission. The NIH appropriation has been reduced by $6.7 million in 1989 and this reduction carries through into the FY 1990 budget. In addition, the FY 1990 President's Budget proposes program reductions of $19 million in the RMS budget, although not specifically related to procurement. Thus, NIH must achieve all possible savings just to offset a portion of the reductions to the NIH budget that have been taken or are proposed to be taken.

PROCUREMENT

Question. Why isn't there a position savings reflected in your budget?

Answer. There is a reduction of 175 non-AIDS FTEs in NIH's 1990 budget related to management improvements. In total, these reductions are offset by increases of 107 FTEs for AIDS and 30 FTEs to establish or expand new entities, such as the new NIDCD, the Office of Human Genome Research, etc. It is difficult to precisely state a portion of this reduction that is specifically related to procurement. However, any savings can be used to offset a portion of this reduction.

At the time our budget was prepared and submitted, we had inconclusive data on the characteristics of NIH's ordering offices and personnel, including the amount of time spent by personnel on purchasing and other duties as well as the number of orders processed per person. Further, we did not have a clear indication on how the conversion to full-time purchasing agents would impact on position savings. The use of full-time purchasing agents was recommended to NIH by the Logistics Management Institute, which indicated that full-time professionals would be able to process orders more efficiently and effectively than if less experienced personnel were utilized. We agree that full-time purchasing agents

should be more efficient and we are pursuing that goal; at the same time, we will also be asking our purchasing agents to perform additional duties beyond the level previously performed.

Since that time, we have performed an exhaustive survey of ordering offices and officials and have collected substantial statistical data. As a result, we developed criteria for the Institutes to meet in realigning their organizational and personnel structure for purchasing, including the maximum use of full-time purchasing agents in centralized procurement components. The objective of the criteria was to define the guidelines for establishing and staffing ordering offices and establish a workload range that a full-time ordering official could reasonably achieve while maintaining a high-quality procurement level.

The Institutes were asked in March to submit reorganization proposals in accordance with the established criteria. Those proposals, which were submitted in mid-April, are currently under review. We will not have a final answer to the position savings question until all of the reorganization proposals are fully evaluated. We expect this evaluation to be completed by early June. The Institutes are expected to implement their realignments within six months after approval. We would be pleased to provide the Committee the results of these reorganization plans once the evaluation is finalized.

Question. Could you tell us a little bit about how NIH plans to validate the savings associated with the reform actions that are being taken?

Answer. NIH's intent to validate savings negotiated with vendors was clear at the outset with the addition of a "list price" data field in all orders. This requirement was established as part of NIH's action plan in June 1988 and was implemented fully in January 1989.

In order to utilize the list price data in verifying receipt of cost savings, NIH developed in early May a monthly discount validation report. This report is based on monthly programmed summary reports which compare the amount paid for each line item with the list price entered into the order. The report highlights those instances where the discounts calculated do not equal the discounts negotiated for the commodity. We believe this process will be highly effective in identifying any discount discrepancies and will help us determine whether discrepancies are a result of noncompliance by the vendor or incorrect input of information at the ordering office level.

We intend to use this monthly report to validate all orders placed since October 1988. If discrepancies are found, we will pursue monetary recovery and impose sanctions on vendors, where appropriate. We are committed to ensuring that NIH receives the total cost savings negotiated through its ordering agreements. This report will assist in that endeavor.

Question. According to the IG's April 1989 report, data on DELPRO savings in personnel positions will not be available until

later this month. What position savings for procurement activities will there be in fiscal year 1990?

Answer. NIH completed a study in early 1989 to determine the appropriate criteria for reorganizing its DELPRO purchasing offices, commonly referred to as nodes. This effort was aimed at evaluating the potential for reducing the number of ordering staff and utilizing full-time purchasing agents to the maximum extent. This study took a little longer to complete than we initially expected. However, we believed that our consolidation effort had to be planned carefully because of the potentially disruptive impact on personnel in the Institutes.

Our study revealed that many personnel were involved in ordering only a fraction of their time. On the surface it appeared to us, as it did to the Logistics Management Institute (LMI), that personnel savings might be achieved by consolidation of positions and functions. However, upon closer analysis, we found that consolidation efforts would achieve savings in efficiency but not necessarily in positions. The following illustrates this point. If ten secretaries in different offices of a Division each spent 10 percent of their time in purchasing activities, it could not necessarily be assumed that any of these offices could part with its secretary to become a full-time purchasing agent. The secretarial function would still be required. Therefore, the consolidation of the purchasing activities of these offices may require a "new" purchasing agent position, allowing the secretaries to devote their total effort to secretarial duties. Such consolidation will, however, reduce the number of people involved in the ordering process and should result in a more efficient purchasing system.

The Institutes were asked in March to submit reorganization proposals in accordance with criteria we established as part of our study. These proposals are currently under review. A definitive answer on the position requirements will not be available until all of the proposals are fully evaluated. We expect to have our evaluation completed by early June and would be happy to submit the results to the Committee when it is complete.

PROCUREMENT

Question. Could you please provide us with a schedule for fiscal years 1988, 1989, 1990, and 1991 showing (1) the number of individuals at NIH performing procurement activities either full or part time and (2) an estimate of the number of staff years of effort devoted to procurement activities in each of these years.

Answer. This answer is presented in three parts to coincide with the three-part system NIH has established for intramural acquisition, including small purchases.

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As part of its procurement reform, NIH has undertaken a study to evaluate the necessity for decentralized offices and to develop appropriate criteria for their establishment.

BUILDINGS AND FACILITIES

Question. The NIH request to the Secretary was for over $100 million for non-AIDS building and facility projects and $30 million for AIDS building and facility projects. The President's request includes only $6.7 million for routine repair improvements and an additional $14.9 million for AIDS-related building projects at NIH. What are two major projects that you had hoped to fund with your original request that have been cut?

Answer. Currently, the two higher priority non-AIDS facilities projects at the NIH for which funding is required are the initial

phase of the Infrastructure Enhancement and PCB Transformer Replacement program and the continuation of the Clinical Center Modernization project. The amount of $19.2 million is necessary for the Infrastructure program to fund the installation of a boiler, replacement of three chillers, design of underground utility tunnels, and the replacement of 37 PCB transformers to eliminate safety hazards and meet EPA regulations. The Clinical Center modernization and safety program involves the installation of sprinklers and areas of refuge, the renovation of two old and inadequate air handling units needed to keep two Clinical Center wings operating and a new Medical Intensive Care Unit needed to provide increased capacity for the AIDS and pediatric programs. This will address shortcomings in safety and provide for modern procedures, equipment, and facilities for quality patient care at an estimated cost of $14.5 million.

CLINICAL CENTER MODERNIZATION

Question. I understand that there has been a modernization program underway for several years at the in-patient wards of the Clinical Center. Eleven of the twenty-nine patient care units have been renovated at a cost of approximately $50 million. What plans do you have for renovating the remaining eighteen patient care wards?

Answer. We have a major review underway of the decade-old Clinical Center Modernization program. While the study is not complete, it is clear that major problems exist in the Clinical Center's utility systems and there are safety problems that have not been adequately addressed. While a long range solution awaits completion of the review, we are undertaking a program in the interim to address the safety and accreditation issues in an accelerated program to complete the remaining patient care units (PCUs) over the next 5 years. This new approach will reduce costs and keep PCU shutdown time to a minimum by designing a generic package that primarily addresses safety and hospital accreditation problems on the PCUs and can be carried out with operating funds. For those projects involving improvements, e.g., fire alarms and Clinical Center utility systems, we will continue to seek buildings and facilities funding.

CONSOLIDATED OFFICE BUILDING

Question. NIH has made a supplemental request for authority to essentially reprogram FY 1989, FY 1990 and FY 1991 funds, not to exceed $96 million, for the construction of a consolidated office building on the NIH campus in Bethesda. I understand this reprogramming authority is an OMB proposal. If the Committee provided you with this authority, would you actually use it? In other words, would you be willing to reduce research project grants from the several institutes in order to finance the construction of this building?

Answer. Consolidating the extramural staff of the NIH on the NIH campus is a very high priority, and the Consolidated Office Building was proposed in order to accomplish this. If the Committee provided NIH with authority to reprogram funds from the Institutes

in order to build the building, we would use that authority, even though research project grants would be a probable source of funds.

FEDERAL DEMONSTRATION PROJECT

Question. For the last two years, the Committee has encouraged NIH's interagency leadership of the Federal Demonstration Project to improve research productivity by field testing streamlined procedures for the administration of research grants and contracts. The key objective is to enable scientists to spend more time on science and less on unnecessary paperwork and administrative requirements. The effort has been called the "Do science" project. What progress has been made by the Federal agencies to implement the successful features of the earlier (Florida) phase of the demonstration?

Answer. The four most successful features of the Florida Demonstration Project (or "Expanded Authorities"), are provided in an OMB Memorandum for the Heads of Executive Departments and Establishments (M-88-20), dated May 18, 1988. All Federal agencies are encouraged to apply these features. The eleven Federal agencies which are participating in the Federal Demonstration Project have adopted all or most of these features.

NIH implemented the following Expanded Authorities as of October 1, 1988 on most of the R series grant mechanisms, the traditional research project grants. These changes allow the grantees to:

- o Incur costs 90 days before the start date of competitive awards.
- o Extend the final grant budget period.
- o Automatically carry over unobligated grant funds from one funding period to the next.
- o Waive cost related prior approvals required by OMB circulars. However, the requirements for allocability, allowability, reasonableness, and consistency of costs remain applicable.

Question. Are there any problems in carrying out or implementing the demonstration which you want to mention to the Committee?

Answer. At this time we are not aware of any major problems.

QUESTIONS SUBMITTED BY SENATOR BURDICK

ADVISORY COUNCILS

Question. As you know, because of the critical relationship between health and behavior, P.L. 100-607 (last year's NIH reauthorization) required that at least two scientists from the behavioral and social sciences or public health be included on NIH Advisory Councils. What is the total number of Advisory Council

seats and how many of those seats are held by behavioral or social scientists?

Answer. The total number of advisory council seats is 192 of which two-thirds, or 128, are by legislation scientific members. It is from these 128 that two representatives from the public health, social or behavioral sciences are to be selected for each of the 12 NIH advisory councils.

There are currently 12 public health, social or behavioral scientists on NIH advisory councils.

Appointments to NIH advisory councils are made by the Secretary, Health and Human Services. Public Law 100-607 was passed on November 4, 1988, by which time nominations and most appointments for 1988 were completed. Nominations for 1989 are in process and are in compliance with P.L. 100-607.

Question. Please describe for the record the current representation of behavioral and social scientists, identified by profession of each NIH Advisory Council, as well as the total number of positions available for appointment by the Secretary for each Advisory Council.

Answer. The following is a list of NIH Advisory Councils, including the number of positions available for appointment, the number of those positions that must be filled by scientific members, and the profession of the member or members who represent the behavioral or social sciences.

National Advisory Council on Aging
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
(1) Professor of Psychology (geropsychology; general psychology)

National Advisory Allergy and Infectious Diseases Council
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
None

National Institute of Arthritis and Musculoskeletal and Skin Diseases
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
None

National Cancer Advisory Board
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
(1) Professor and Dean, Department of Communication (persuasion and social change; language behavior; evaluation research)

National Advisory Child Health and Human Development Council
Positions available for appointment: 15 members; 10 scientists
Current representatives of behavioral and social sciences:
(1) Professor of Psychology (child clinical psychology)
(2) Professor of Psychology and Pediatrics (mental

retardation; child development; behavioral pediatrics; behavioral epidemiology)

National Advisory Dental Research Council
Positions available for appointment: 12 members; 8 scientists
Current representatives of behavioral and social sciences:
(1) Professor, Rehabilitation Medicine (clinical psychology; behavioral medicine)
(2) Professor and Director of Dental Hygiene Programs (behavioral science; instructional psychology)
(3) Executive Assistant to the President, University of Texas Health Science Center (psychology of reading; child development)

National Diabetes and Digestive Diseases and Kidney Diseases Advisory Council
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
None

National Advisory Environmental Health Sciences Council
Positions available for appointment: 15 members; 10 scientists
Current representatives of behavioral and social sciences:
None

National Advisory Eye Council
Positions available for appointment: 12 members; 8 scientists
Current representatives of behavioral and social sciences:
(1) Associate Professor, Department of Optometry (public health; epidemiology; biostatistics)

National Advisory General Medical Sciences Council
Positions available for appointment: 12 members; 8 scientists
Current representatives of behavioral and social sciences:
(1) President, Carnegie Mellon University (behavioral science)

National Heart, Lung, and Blood Advisory Council
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
(1) Director, Office of Minority Affairs (public health; urban health problems; environmental health issues)

National Advisory Neurological Disorders and Stroke Council
Positions available for appointment: 18 members; 12 scientists
Current representatives of behavioral and social sciences:
(1) Senior Research Psychologist (sensory psychology; cutaneous sensitivity; psychophysics; aids for the handicapped)
(2) Professor, Community and Family Medicine (social work; public health)

Current public health, social and behavioral science representation totals 12.

RESEARCH ON AGING

Question. Dr. Williams, we know that the fastest growing segment of our population is the "oldest old," those aged 85 and over. Is NIA supporting any research that will maximize and extend

the independence and productive lives of these people, as well as their younger 65 and over counterparts? I have in mind such areas as research on the work environment, transportation systems, and improvements in the home environment for the frail elderly.

Answer. The oldest-old population (those aged 85 and over) is indeed growing faster than any other age group. Moreover, preliminary but dramatic findings from new research projects indicate that official Census projections may substantially underestimate the size of future cohorts. In the last three or four years, NIA-funded researchers have made considerable progress in characterizing the functional status of the oldest-old and in identifying both modifiable and non-modifiable risk factors for transitions between independence and dependence. Also, important surveys (such as the Longitudinal Study on Aging and the National Long Term Care Survey) are providing essential data for an expanding group of researchers to examine such topics as assessments of the ability of those aged 70 and over to move around the community, the importance of the architecture of the dwelling unit to functioning, and social activities relevant to maintained independence.

NIA is also increasing its long-standing interest in extending the independence and productive lives of older adults through an initiative on "Reducing Frailty and Injuries in Older Persons" that calls for environmental interventions to reduce injury risk and through an initiative on human factors research. The key concept in this latter initiative is an elder-friendly environment. Many design standards for highway systems, work environments, and home appliances are anchored around the performance of younger adults. Sharp performance differences exist between younger adults and particularly oldest old adults. Therefore, the human factors initiative seeks to study older people in home, work and transportation systems to discover principles that allow these environments to become elder-friendly.

In this research area, an initiative is already underway to investigate the needs and problems of older drivers. A workshop (jointly sponsored by NIA, the National Highway Traffic Safety Administration, the Federal Highway Administration and the Centers for Disease Control) will be held in August 1989 to develop a research plan for this population. Additionally the National Highway Traffic Safety Administration and NIA are collaborating on a project to obtain and relate driving practices and driving records in two populations, the Iowa 65+ Rural Health Study and the Yale Health and Aging Project. These are two of the Established Populations for Epidemiologic Studies of the Elderly (EPESE), a multi-center, prospective study of 14,000 older Americans initiated to plan and conduct disease-oriented epidemiologic investigations. The data being collected on older drivers will be used to determine the impact of medical conditions and functional capability on a person's driving and walking.

Several currently funded studies are also providing answers to questions on independence and productivity. One study examines how psychologists, architects and clinicians can collaborate to reduce environmental demands on Alzheimer's patients living at home. Other work focuses on understanding the current epidemic of early retirement among older males in the workforce. For example, one study has found evidence that strongly suggests that for a number of

large companies, certain structuring of benefits under the private pension system leads to early retirement--despite attempts by the Social Security System to counteract this trend. Even with these important but isolated findings, research on retirement has been severely hampered by the lack of any adequate current national data. To correct this severe gap in information, a new survey is proposed for FY 1990 on Health and Retirement.

Continuation of the initiative on Human Factors and implementation of the planned new survey on Health and Retirement will continue to provide useful answers to these important questions of productivity and independence of the oldest old population.

HEALTH AND BEHAVIOR RESEARCH

Question. An extensive research program on diet and cancer continues to probe the role of specific foods and food groups to find ways of preventing cancer through dietary modification. What is being done by NIH to put the knowledge gained from this research to work--to influence a change in the eating behavior patterns and food choices of high-risk minority Americans?

Answer. Several actions are being taken by the National Cancer Institute (NCI) to influence a change in eating behavior patterns.

Thirty-five percent of all cancer deaths may be attributable to diet and nutrition. Minority populations in particular are at high risk, and are disproportionately affected by problems related to diet and nutrition. The NCI's Division of Cancer Prevention and Control (DCPC) has launched an extensive program to determine the factors contributing to poor cancer survival among blacks, and to change diet and nutrition habits among minorities, as well as the majority population.

The Black/White Survival Study is following a cohort of over 3,400 cancer patients, equally divided between blacks and whites, to assess the survival benefit that can be attributed to various explanatory factors such as: knowledge, attitudes, and practices regarding dietary behavior, practices regarding prevention and early detection, and other factors.

Based on knowledge gained from diet, nutrition and cancer studies, and from studies such as the Black/White Study, several projects have been initiated to influence a change in the eating behavior patterns and food choices of high-risk minority Americans.

Super market studies are assessing the effects of in-store fat and fiber content information on purchasing behavior, and three community-wide projects are studying effective ways of modifying eating behaviors.

Several school lunch programs are aimed at changing the eating patterns of the young. These include the promotion of nutrition education programs, the development of guidelines for school lunch managers, and widespread publication of the curricula and guidelines for use by school principals and administrators.

In addition, the NCI, in collaboration with the American Dietetic Association, and the American College of Physicians, has

published the pamphlet "Nutrition Guidelines for Family Physicians." These will be widely disseminated, and will enable physicians to counsel their patients about appropriate food choices and eating behaviors.

Question. Similarly, what behavior change research and programs, specifically, are you undertaking to influence Americans, particularly minorities and youth, to change their smoking behavior?

Answer. Approximately 30 percent of all cancer deaths are smoking related. More than 100,000 pre-teenagers are habitual smokers, and as many as 4,000 youths begin smoking every day.

In response to this overwhelming problem, the NCI established the Smoking, Tobacco, and Cancer Program (STCP).

The STCP reaches approximately 10 million people through school-based programs, using self-help materials and the media, and by involving physicians and dentists as interveners. The prime target populations are adolescents, women, Blacks and Hispanics, smokeless tobacco users, and heavier smokers. In addition, the STCP has developed consensus documents and manuals for prevention-cessation intervention to reduce smoking and tobacco-use prevalence. These are only a portion of the results of the 60 clinical trials still underway testing the most effective ways to control tobacco use.

Eight school-based trials reach approximately 179,000 students in grades three through twelve. The goal of these projects is the development and dissemination of school based curricula. The eight projects include:

- "A Comprehensive Approach to the Prevention of Smoking"
- "Late Adolescent Smoking: Process Analysis and Deterrence"
- "School and Family Oriented Cancer Prevention Program"
- "Evaluation of School-Based Smoking Prevention"
- "A Statewide Approach to Adolescent Tobacco-Use Prevention"
- "Smoking Prevention: The Youth Health Promotion Project"
- "Longitudinal Evaluation of a School Anti-Smoking Program"
- "Smoking Prevention Training for High Risk Youth"

Several projects address the problem of smoking among minority youth, including a project for life skills training for junior high school black students in Newark, New Jersey. Similar projects are planned for other minority youths.

STCP projects already include 166 scientific publications in peer-reviewed scientific journals, and several hundred manuals, guidelines and protocols produced by the investigators leading these trials. In addition, the following manuals have been produced, and represent NCI-endorsed consensuses:

- "Essential Elements of School-Based Smoking Prevention Programs"
- "Smoking Control Media Advocacy Guidelines"
- "How to Help Your Patients Stop Smoking: The National Cancer Institute's Manual for Physicians"
- "Guia Para Dejar de Fumar"
- "Healthy Breathing, an HMO-physician Based Cessation Program"

Two large-scale community studies have begun. The first, the Community Intervention Trial for Heavy Smokers (COMMIT) completed its two years of planning and began a full-scale implementation in 11 communities in North America. This trial, the largest ever of its kind involving heavy smokers (those at greatest risk for cancer), will impact well over two million individuals.

Manuals developed by COMMIT investigators are being tested, and will be published at the completion of the trial. These include:

- "Handbook for Community Change"
- "Publication Education Resource Kit"
- "Working with Unions to Reduce Cigarette Smoking"
- "Forming Partnerships with Religious Organizations"
- "A Guidebook for Conducting Incentive Programs for Smoking Cessation in Community Organizations and Worksites"

A second trial, the American Stop Smoking Interventions Study (ASSIST), seeks to accelerate the reduction of tobacco use in the United States by applying tested tobacco control interventions and other control measures through regional tobacco control coalitions. This project will involve states and/or large metropolitan areas and impact more than 50 million Americans. It will be the largest public health demonstration ever conducted by the Public Health Service.

HEALTH AND BEHAVIOR RESEARCH

Question. Are we conducting studies to determine how best to change these deeply ingrained human behaviors, and what do we know about how best to: 1) add a behavior to improve health, such as incorporating exercise into our lifestyles; 2) change human behavior patterns, such as modifying high-risk eating habits; and 3) eliminate a high-risk behavior, such as smoking? Are mechanisms in place to evaluate the success of your efforts to improve public health by changing these behavior patterns?

Answer. The NCI has a major investment in the area of health and behavior, including research aimed at changing human behavior patterns, such as modifying high risk eating habits; and eliminating high risk behavior, such as smoking. Every NCI study contains an evaluation of the study's effectiveness in changing the behavior it addresses.

The aforementioned Smoking and Tobacco and Cancer Program (STCP), as well as the Community Intervention Trial for Heavy Smokers (COMMIT) and the America Stop Smoking Intervention Study (ASSIST), are aimed at improving health through a change in behavior.

The previously mentioned Super Market studies are assessing the effects of in-store fat and fiber content information on purchasing behavior, and three community-wide projects are studying effective ways of modifying eating behaviors.

In the area of screening and early detection, NCI conducts research ranging from the evaluation of potential screening technologies, to the evaluation of information and dissemination programs. It has been shown that mass screening for breast cancer

by mammography and physical examination, and for cervical cancer by pap smear is effective. Techniques to detect other cancers earlier are also under investigation. However, in all of this effort, it is clear that the human behavior variables are of considerable importance.

In collaboration with the American Medical Association, the American College of Obstetrics and Gynecology, the American Society of Internal Medicine, the American Urologic Association, the American Academy of Dermatology, and the American Society of Otolaryngologists, the NCI forged a consensus of Working Guidelines of early detection for seven cancer sites.

Studies are in process to determine the most effective ways to influence provider and patient behavior to increase the use and effectiveness of screening and detection techniques. These studies are particularly interested in increasing utilization among minorities, and in influencing the behavior of practitioners through State and local health departments, HMOs, and primary care settings.

Community oncology programs address diffusion of state-of-the-art treatment protocols, and problems associated with rehabilitation. Studies in the more than 52 community programs in 30 states are investigating both the determinants of physician behavior, and how to influence this behavior; and ways of improving patient (especially minority) access to and use of available care.

In the area of rehabilitation and quality of life, studies are under way to improve the quality of life for children. Studies include school attendance, and employment and insurance issues.

One study is seeking to identify the needs for and the availability of home care for cancer patients, as well as identify the characteristics of patients who do and do not participate in self-care activities. A complementary program studies nursing intervention to promote the ability of patients undergoing chemotherapy or radiotherapy to take an active role in managing their own care.

Clinical trials are assessing the use of heroin to control pain, and studies are planned to improve the physician's ability to manage pain, and enhance the patients' ability to cope with treatment side effects.

Since 1976, 25 regional Cancer Information Service (CIS) offices provide information to the general public and health professionals on cancer causes and prevention, detection, treatment and rehabilitation, and on diet and smoking.

The CIS is accessible to over 85 percent of the U.S. population, and each year more than 350,000 information requests are received. Sixty-thousand of these concern smoking and tobacco use.

The National Heart Lung, and Blood Institute (NHLBI) is actively pursing answers to the question of how best to change behavior to reduce the major modifiable risk factors for cardiovascular disease (CVD) and thus reduce death and disabilities from CVD. This is being pursued in communities, in schools and in the workplace.

Most of the school-based studies involve randomization of schools to treatment and control conditions. Multi-disciplinary research teams address one or more of the following risk factors: nutrition, exercise, smoking, high blood pressure, and stress. The studies will collect information on knowledge, attitudes, behavior, and physiological measures, such as, weight, blood pressure and blood cholesterol levels. Several of the studies focus on school policy and procedure changes related to school cafeteria food content and preparation and physical activity opportunities for children. The grade levels range from third to tenth. Some of the projects have a family or parent component to the study. In a large number of studies, major racial and ethnic minorities comprise the study populations.

The NHLBI is funding three investigator-initiated community-based research and demonstration programs designed to reduce risk of cardiovascular disease (CVD) through a population-wide approach to primary disease prevention. By multiple education and evaluation strategies, the programs help communities choose and practice more healthy behaviors and enhance community efforts to support these behaviors. The three projects were established to develop and assess the effectiveness of community-based programs to prevent atherosclerotic heart disease by modifying behaviors and therefore risk factors that contribute to the development of this disease. The specific risk factor targets include smoking, cholesterol-elevating diets, high blood pressure, obesity, and physical activity. The major aim of the studies is to test the hypothesis that a significant decrease in the multiple logistic risk for the educated communities will lead to a decline in morbidity and mortality from cardiovascular disease beyond that attributable to the secular term.

In research projects in the worksetting for CVD prevention and health promotion, an attempt is made to define efficient interventions for CVD risk factor reduction. Efforts directed toward high blood pressure control among male employees in white-collar settings have been generally successful. Currently funded projects seek to extend worksite programs to other risk factors (smoking, weight control, cholesterol reduction) and to reach blue-collar and minority workers.

On-going projects include intervention efforts in auto manufacturing plants, a program for employees in a large southern city, and smoking cessation and obesity control programs located in 30 medium-sized firms to test different types of incentives for risk factor reduction, and a project to hasten return to work after myocardial infarction.

The NHLBI's two major national education programs, the National High Blood Pressure Education Program (NHBPEP) and the National Cholesterol Education Program (NCEP), both have components that address the control of these risk factors through dietary change. The NHBPEP has targeted specific messages to the black population, because of the high prevalence of hypertension in this group.

In addition, the NHLBI school-based cardiovascular disease risk reduction studies are investigating the effectiveness of efforts to change habits for nutrition, exercise and smoking through programs established in the school environment. In several of these studies

the school populations have substantial racial and ethnic minorities. In the workplace, the Institute currently is funding projects that attempt to reach blue collar and minority workers to establish successful efforts for blood pressure control, reducing high blood cholesterol and stopping smoking.

The National Institute of Child Health and Human Development has conducted and supported several projects dealing with changing high-risk behavior, especially smoking. These include:

- Social Psychological Factors in Adolescent Smoking
- Pregnancy, Parenting and Drug Use
- Food Intake, Smoking, and Diet Among Adolescent Girls
- NICHD Smoking Trial of Pregnant Women

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

HEALTH AND BEHAVIOR RESEARCH

Question. Dr. Wyngaarden, last year the Committee asked you to report to us on your health and behavior research initiatives, which we have consistently asked you to increase. I am concerned that the proportional increase in NIH funds dedicated to health and behavior research that we have wanted to see for so many years is again not reflected in your report. I would like to hear from you about that now.

Answer. As noted in our recent report to Congress on Health and Behavior Research Initiatives by the National Institutes of Health, FY 1989, the NIH recognizes the important role played by behavior and social factors in all aspects of illness and health, particularly the prevention of illness and the promotion of good health. The funding level for health and behavior research increases by 6 percent from FY 1988 to FY 1989. This is consistent with the growth in the non-AIDS budget for the NIH.

It is difficult to state what the optimal funding level for behavioral research should be, since it varies from one health area to the next. Each NIH Institute determines for its areas of research the appropriate balance between behavioral and biomedical research. While behavioral research is an important area of research, in times of increasing emphasis on basic research and burgeoning scientific opportunities, difficult choices must be made among high priority programs depending on the opportunities.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

RESEARCH PROJECT GRANTS

Question. I don't know what decision the Committee will make regarding the consolidated AIDS account, but for the purposes of discussion I would like to talk about the $6.777 billion budget request for NIH which excludes funding for AIDS-related activities. I understand that this level of funding will support 4,456 new and competing research awards. Is that correct? How does that level of

awards compare to FY 1989 and FY 1988? What funding would be necessary to maintain at least FY 1989 levels of new and competing awards?

Answer. The FY 1990 President's request would support 4,456 competing research project grants, excluding AIDS. In addition, approximately 100 competing grants may be funded through the Director's Discretionary Fund. This level compares to the 5,128 competing awards in the FY 1989 estimate and 6,006 in FY 1988.

An additional $76.1 million would be required in FY 1990 to maintain the FY 1989 level of 5,128 competing research project grants at the comparable level of downward negotiations.

CURRENT SERVICES

Question. What appropriation would be necessary to support current services? Was your official budget submission to the Public Health Service a current services budget? If not, what was your original non-AIDS budget request?

Answer. The NIH calculated current services budget estimate is $7.352 billion. The current services figure which appears in the President's FY 1990 budget would be $7.044 billion which excludes estimates for salaries. Our official budget submission to the Public Health Service was not a current services budget and totalled $9.178 billion for non-AIDS.

RESEARCH PROJECT GRANTS

Question. I understand the FY 1990 budget request would allow NIH to fund only about the top quarter of investigator-initiated grants. Is that percentage of funded grants constant or declining? What percentage of grants was NIH funding in 1980? in 1985? in 1986?

Answer. The FY 1990 request for competing research project grants would permit NIH to fund about 24 percent of the applications recommended for approval, a decline from the award rate of 29 percent estimated for FY 1989 and 35 percent in FY 1988.

In FY 1980, NIH funded about 42 percent of the research project grant applications recommended for approval, 37 percent in FY 1985 and 36 percent in FY 1986.

Question. I understand that an across-the-board reduction is being made in all grants. How is this across-the-board reduction affecting competing and noncompeting grantees? What would it cost to reduce the size of the cut made in each grant from 10 percent to 5 percent, for example.

Answer. In the FY 1990 request, the NIH aggregate downward negotiations for noncompeting and competing research project grants, excluding AIDS, are 8.7 and 9.6 percent, respectively. The Institutes would not be required to apply their downward negotiations across-the-board; they would have the latitude to apply reductions selectively in accordance with their program priorities and budget.

An additional $171.4 million would be required to reduce the aggregate downward negotiation levels to 5 percent for both noncompeting and competing research project grants.

RESEARCH TRAINING

Question. What would be the cost in FY 1990 of returning to the FY 1988 level of approximately 11,200 trainees? Did your original budget submission to the Public Health Service include funding to pay 11,200 trainees at the increased stipend level? If not, why not?

Answer. Approximately $281.6 million would be required in FY 1990 to support the same number of trainees as in FY 1988. This is an increase of $28.8 million over the FY 1990 President's Budget request.

The NIH FY 1990 budget submission to the Public Health Service included funds to support 12,300 trainees, excluding AIDS, at the increased stipend level.

RECRUITMENT AND RETENTION

Question. I've heard some appalling statistics about your recruitment and retention problems at NIH because of the salaries of senior researchers. Is pay the only issue or are other issues such as retirement benefits and work environment also important?

Answer. While pay is the primary issue in our ability to recruit and retain senior scientists, there are other concerns. Academia offers a portable retirement system to their senior scientific staff, facilitating employment shifts within academia, and making Federal employment less attractive. Another issue is the difficulty of retaining senior scientists when their children reach college-age and tuition costs become a major economic consideration. Employment in academia then becomes even more attractive, because tuition supports and subsidies are common. Other benefits that NIH cannot offer include attractive stock options and the use of company cars.

NIH is continuing to develop a legislative proposal that would establish the Senior Biomedical Research Service. The latest NIH proposal includes provisions to link salaries to academia, and establish a portable retirement system. The proposal is currently being reviewed by the Department of Health and Human Services.

Question. Assuming, the Senior Biomedical Research Service proposal is approved, what would it cost to fund it in FY 1990?

Answer. The NIH estimates that the additional first year cost for the Senior Biomedical Research Service, which would make senior NIH scientific salaries competitive with the private sector, would be approximately $12.7 million.

NURSE RECRUITMENT

Question. Last year, the Congress provided new flexibility in your ability to recruit nurses and allied health specialists. What has been the impact of your recruitment efforts?

Answer. Since July of 1986, NIH has had legislation (Title 38 authorities) to keep Clinical Center nurses' salaries at rates that will provide adequate staffing levels, including recruitment of personnel with specialized skills. Base pay levels have been increased and premium pay provisions have been broadened, for example on-call duty. NIH has already noticed improvements in both recruitment and retention in the Nursing Department. On-board FTEs have increased by approximately 25 percent. The vacancy rate has decreased from 10 percent to a current vacancy rate of 7 percent. Also, since implementation of the legislation, the turnover rate for nurses has dropped from 25 percent in 1986 to 17 percent in 1988.

In September of 1988, NIH received legislative authority to similarly improve staffing and recruitment of Clinical Center allied health professionals. To date, special pay rates and broadened premium pay provisions have been implemented for seven of the allied health occupations. Other allied health occupations have received or will be receiving increased compensation as a result of the broadened premium pay provisions. Because these pay authorities have been implemented so recently, and because of the diversity and severity of staffing problems across the various occupations, it is too early to quantify the impact on recruitment and retention. However the positive impact of the legislation for allied health occupations is becoming apparent. Some examples are:

- Implemented and anticipated compensation increases have had a positive effect on the morale of employees and managers.

- Knowledge of Title 38 pay authorities is reaching potential candidates. Clinical Center departments are receiving greater responses to employment advertisements than previously, and more unsolicited candidates are inquiring about employment. Managers feel that many of these applicants possess better qualifications than has been typical of NIH applicants for several years.

- Allied health employees are less vocal about seeking other employment and are beginning to view NIH employment in "career" terms and are making significant personal plans accordingly, for example, buying a home or making major investments.

- Several employees have changed their plans about leaving the Clinical Center, and three have returned due to changes resulting from the legislation.

AIDS DRUGS AND THERAPIES

Question. How many different drugs and therapies are currently in trials? Are there any drugs that received high ratings from the drug review committees but are not in trials because of lack of personnel or funds?

Answer. In the AIDS program at the present time, approximately 30 drugs are under study alone or in combination, including anti-HIV agents, biologic response modifiers, and drugs for opportunistic infections. One hundred different studies have been started, and most of these remain open to patient enrollment.

Drugs submitted from various sources are reviewed by the AIDS Clinical Drug Development Committee and prioritized for entry into studies. All but two agents given high priority and several accorded medium priority have been entered into trials. The two high-priority drugs DFMO and erythropoietin are not in trial within the NIH system because the sponsors wished to conduct their own studies utilizing private resources.

AIDS CLINICAL TRIALS

Question. What is the geographic distribution of persons participating in clinical trials? What programs are being undertaken to assure a wider distribution of access to clinical trials for rural communities and urban centers without an AIDS Clinical Trials Group program?

Answer. The National Institutes of Health is conducting clinical trials across the country through the extramural program of the National Institute of Child Health and Human Development and the AIDS Clinical Trials Group (ACTG) of the National Institute of Allergy and Infectious Diseases. Larger, multi-center trials and some smaller, single-institution studies are conducted by 46 units of the ACTG located in 17 states and the District of Columbia. Thirteen of these units, 11 of which were established in October 1988, are devoted solely to pediatric studies. In addition, the NICHD supports clinical trials at 26 centers.

In November 1988, the NIAID established the new Community Programs for Clinical Research on AIDS to involve community physicians in AIDS research. These programs will broaden the base of the NIH clinical trials by including primary care physicians who are not affiliated with established centers and who are providing care to a number of HIV-infected persons not generally served by such centers. Through the community programs, NIH hopes to include in clinical trials more HIV-infected black and Hispanic persons, intravenous drug users, and women. In June 1989, the AIDS Program Advisory Committee of the NIH will examine the current problems in access to clinical trials for underserved populations and make their recommendations to the NIH Director.

Question. How many patients are participating in the NIH's clinical trials program? How many have participated over time and how many are currently enrolled in protocols? What level of expansion is anticipated in the 1990 budget?

Answer. As of May 1, 1989, more than 6,800 patients have participated in clinical trials of the AIDS Clinical Trials Group. The NICHD has enrolled another 300 and over 500 patients have been treated in intramural trials at the NIH Clinical Center. Enrollment varies over time due to the diverse nature of the studies, which vary from short-term protocols to continuous programs of ongoing treatment. Some patients are enrolled in more than one study.

In May 1989, the NIH inaugurated the AIDS Clinical Trials Information Service as a central resource for current information on NIH funded clinical trials for AIDS patients and others infected with HIV. Experienced health specialists can provide physicians and

patients with the latest information on clinical studies, their locations, and eligibility requirements. It is hoped this service will encourage enrollment in clinical trials by bringing information to every community with this toll-free telephone number.

The NIH FY 1990 budget represents an increase for clinical trials of more than one-third over FY 1989.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

BUDGET REQUEST

Question. Dr. Wyngaarden, what was the original NIH budget request submitted to the Public Health Service for FY 1990? How does that compare with the request before us today? What was the original request for each Institute? How much does the NIH need to maintain current services in FY 1990?

Answer. The original NIH budget request to the Public Health Service for non-AIDS funding for FY 1990 was $9.178 billion. That request was $2.402 billion or 35 percent higher than the $6.776 billion President's budget request. The FY 1990 request to the Public Health Service was submitted in total for NIH and, therefore, is not available at the Institute level. The NIH current services budget estimate is $7.352 billion. The current services figure which appears in the President's FY 1990 budget would be $7.044 billion, which excludes the estimate for salaries.

The original NIH budget request to the Public Health Service for AIDS funding for FY 1990 was $990.2 million. That request was $237 million or approximately 32 percent higher than the $752.7 million President's Budget request. NIH would be able to maintain current services for AIDS at the President's Budget level and fund a modest program expansion.

CLINICAL TRIALS

Question. Dr. Wyngaarden, how many new clinical trials were approved in FY 1989? How many were funded? Which ones were not? How many will you be able to fund with the President's FY 1990 request? Which ones will not get funded?

Answer. We have identified 122 major new clinical trials at approximately $154.2 million that could be undertaken if FY 1989 funds were available. Of these, we estimate that we will begin 50 major new clinical trials at approximately $43.6 million. Those clinical trials that we will be unable to fund in 1989, at an estimated cost of $110.6 million, are listed on the following pages. We estimate that we will be able to fund 17 major new clinical trials for approximately $38.6 million within the FY 1990 President's Budget. Another 146 major new clinical trials totalling $184.6 million are ready to begin if funds were available. The FY 1990 clinical trials are listed on the following pages.

MAJOR NEW CLINICAL TRIALS THAT WILL NOT BE FUNDED IN FY 1989

(Dollars in thousands)

NON-AIDS

NCI	FY 1989 Amount
Clinical Cooperative Groups - Increased Patient Accrual for High Priority Trials	$3,600
Full Funding of Growth Factor/Anti-Oncogene Therapy Trials	1,500
Additional Phase I/II Trials of Newly Characterized Biological Response Modifiers for the Treatment of Various Cancers	4,000
Developmental and Clinical Testing of Monoclonal Antibodies	5,000
Use of Adoptive Immunotherapy in Additional Cancer Types and Use as an Adjuvant Treatment Including LAK/IL-2 Studies	4,594
Increased Support for Clinical/Comprehensive Cancer Centers	15,000
Increased Accrual to Double Patient Entry in Clinical Trials	16,000
Studies of the Efficacy of Hyperthermia in Cancer Treatment Protocols	1,000
Boron Neutron Capture Therapy	1,000
Increased Participation in Prevention Trials by Community Clinical Oncology Program	2,800
Total, NCI	54,494
NHLBI	
Alcohol Restriction in Treatment for Hypertension	246
Membrane-Active Agents to Prevent Sickle Cell Disease	500
Effect of Digitalis on Survival in Patients with Chronic Heart Failure	200
Sleep Apnea Intervention Trial	2,070
Therapy in Patients with Peripheral Artery Disease	1,000
Pharmacologic Intervention of Adult Respiratory Distress Syndrome	750
Pilot Study of Treatment for Silent Myocardial Ischemia	1,950
Antiarrhythmics and Beta-Blockers Study	2,000
Management of Elevated Blood Pressure in Children	2,300
Treatment of Idiopathic Fibrotic Lung Disease	1,000
Differential Efficacy and Safety of Antihypertension Drugs in the Treatment of Hypertension	1,500
Trial of Fish Oils for the Prevention of Chronic Heart Failure	3,000
Childhood Asthma Intervention Study	1,782
Total, NHLBI	18,298
NIDR	
Use of Adhesive Sealants to Restore Root Surface Caries Lesions	100
Use of Remineralizing Solutions to Reverse Incipient Caries Lesions	100
Testing of Alternative Preventive Measures for the Prevention of Dental Disease in Individuals with Limited Ability to Perform Appropriate Oral Hygiene Procedures and Limited Access to Routine Dental Care	225
Evaluation of the Impact of Alternative Restorative Modalities on the Mortality of Teeth in Adults	200
Total, NIDR	625
NIDDK	
Diet and Exercise in the Prevention and Treatment of Noninsulin-dependent Diabetes Mellitus	500
Enzyme Replacement Therapy in Severe Combined Immunodeficiency Disease	300
Drug Therapy of Chronic Disabling Diarrhea	1,200
Use of Erythropoietin in Pediatric Patients with Renal Failure	1,000
Impact of Dialysis Efficiency in Response to Erythropoietin Treatment	250
Pharmacologic Prevention of Cholesterol Gallstones During Rapid Weight Lose Regimens	1,300
Treatment of Primary Biliary Cirrhosis Using Ursodeoxychiolic Acid	1,000
Nutritional Therapy in Cystic Fibrosis	300
Therapy of Children with Short Stature Due to Growth Hormone Deficiency	1,000
Neonatal Diagnosis of Cystic Fibrosis	750
Total, NIDDK	7,600

	FY 1989 Amount
NINDS	
Efficacy and Metabolism of Anticonvulsants in Neonates	197
Methylprednisolone Therapy in Guillain Barre Syndrome	1,022
Treatment of Intractable Epilepsy with Intravenous Gammaglobulin	337
Shifting Human Circadian Rhythms by Entrainment with Full Spectrum Light	150
Treatment of Attention Deficit Hyperactivity Disorder (ADHD) in Tourette Syndrome	245
Narcolepsy: Pathophysiology and Pharmacotherapy - Project I - Treatment Efficacy Studies	158
Efficacy of Surgery versus Drug Treatment for Epilepsy	198
Therapeutic Trials of Excitotoxin Antagonists in Amyotrophic Lateral Sclerosis (ALS)	394
Tolerability of Ascending Doses of Dextromethorphan in Patients with Partial Seizures	250
Total, NINDS	2,951
NIAID	
Efficacy Trial for Acellular Pertussis Vaccines	1,455
Efficacy Trial of Live, Attenuated, Quadravalent, Oral Rotavirus	1,236
Efficacy Trial of Hib Conjugate Vaccines	597
Genital Herpes Vaccine	265
Randomized Controlled Clinical Trial of Pneumococcal Immunization Using Linked Records to Assess Outcome	1,358
Cyclosporine A Treatment of Pulmonary Sarcoidosis	500
Efficacy Trial of Influenza A Vaccine	800
Total, NIAID	6,211
NICHD	
Calcium Supplementation in Pregnancy for the Prevention of Hypertension, Preeclampsia, and Preterm Birth	1,000
Safety, Immunogenicity, and Efficacy of Pertussis Toxoid Vaccine in Infants (expansion vaccine purchase)	2,500
Pertussis Toxoid in 18-Month Old Children in Sweden (expansion)	150
Prematurity and Gestational Genitournary Infections (expansion)	500
Effects of Maternal PKU on Pregnancy Outcome (expansion)	300
Antibiotic Prophylaxis at the Time of IUD Insertion (expansion)	500
Vitamin E Supplementation (expansion)	200
Incidence and Severity of Neonatal Intracranial Hemorrhage in LBW Infants (expansion)	150
Adjunctive Antibiotic Treatment in Preterm Labor with Intact Membranes (expansion)	100
Prevention of SIDS in LBW Infants	3,500
Total, NICHD	8,900
NEI	
Cryotherapy for Retinopathy of Prematurity Follow-up Study	1,500
Quality of Life Measurement in Glaucoma Treatment Study	1,150
Endophthalmitis Vitrectomy Study	1,000
Total, NEI	3,650
NIAMS	
Efficacy of 13-Cis Retinoic Acid and Other Retinoid Derivatives in the Treatment of Keratinizing Disorders	1,000
Efficacy of Sulfasalazine in the Treatment of Reactive Arthritis	375
Use of Retinoids in the Treatment of Psoriatic Arthritis	500
Efficacy of Calcitonin in the Treatment of Osteoporosis	500
Total, NIAMS	2,375
Total (Non-AIDS), NIH	105,104
AIDS	
NHLBI	
Treatment of Pneumonocystic Carinii Pneumonia	600
NICHD	
Intravenous Immunoglobulin (IVIG) in the Treatment of Children Infected with HIV (Expansion)	4,900
Total (AIDS), NIH	5,500
Total (Non-AIDS and AIDS), NIH	110,604

MAJOR NEW CLINICAL TRIALS TO BE FUNDED AT THE FY 1990 REQUEST LEVEL
(Dollars in thousands)

NON-AIDS

NCI	FY 1990 Amount
Expansion of Multi-institutional Diagnostic Imaging Trials (RDOG III)	$900
Correlation of Laboratory Measure of Drug Resistance.	1,500
Expanded Trials of Gene Therapy Using Tumor Infiltrating Lymphocytes	350
Intervention Study in Patients with Background of Colonic Polyps	3,800
Phase I Studies of New Chemopreventive Agents	1,200
Total, NCI	7,750
NIA	
Urinary Incontinence in Community--Dwelling Women	560
Drugs and Biologicals for the Treatment of Symptoms of Alzheimer's Disease	265
Total, NIA	825
NIDCD	
Development of a vaccine for the treatment of otitis media	2,145
Diagnosis and treatment of inner ear fluid leaks, a newly recognized cause of sudden deafness	1,120
Total, NIDCD	3,265
NCNR	
Reducing Frailty and Injuries in Older Persons	600
Total, NCNR	600
TOTAL, MAJOR NEW IN FY 1990	12,440

MAJOR NEW CLINICAL TRIALS TO BE FUNDED AT THE FY 1990 REQUEST LEVEL
(Dollars in thousands)

AIDS

NCI	FY 1990 Amount
Evaluation of Immunoadhesions in Children with HIV	$200
Evaluation of Immunoregulatory Agents in children with HIV infection	2,900
Combination of DDC Therapy with/without CD4	200
Total, NCI	3,300
NIAID	
Community Programs for Clinical Research on AIDS, specifically intended to broaden the base of our clinical research efforts by including community physicians and their patients	6,000
Expanded Clinical Trials aimed at the pediatric population	3,750
Minority/Geographic AIDS clinical trial to expand the opportunity for underrepresented and under served populations	8,082
AIDS Vaccine Evaluation Unit to test candidate vaccines and to determine the safest dose that will elicit the maximal immune response	5,000
Total, NIAID	22,832
TOTAL, MAJOR NEW IN FY 1990	26,132
TOTAL, NON-AIDS AND AIDS CLINICAL TRIALS IN FY 1990	38,572

MAJOR NEW CLINICAL TRIALS READY TO BEGIN IN FY 1990
IF FUNDS WERE AVAILABLE
(Dollars in Thousands)

NON-AIDS

NCI	FY 1990 Amount
Adjuvant Therapy in Solid Tumors, Including Breast and Colon	$4.000
Increase Patient Accrual Onto National High Priority Trials in Breast, Lung, and Colon Cancer	6.000
Expansion of Tumor Infiltrating-Lymphocyte (TIL) Clinical Trials (Extramural)	1.000
Trials Using Adoptive Immunotherapy	4.594
Phase I/II Trials of Biological Response Modifiers	
--Active Specific Immunotherapy	500
--Monocyte/Macrophage in Anti-Tumor Therapy	500
--Toxins Linked to Targeting Molecules	500
Breast, Ovarian Cancer, Anti-her-2/NEU Receptor Monoclonal Antibody Trial	150
Proton Particle Beam Therapy	1.000
Photodynamic Therapy	1.000
Phototherapy of Mesothelioma	150
Hyperthermia Clinical Trials	1.000
Boron Neutron Capture Therapy Clinical Trials	1.000
Phase II Study of Ara AC in Brain Tumors	2.000
Phase II Study of Thiotepa and Carboplatin	2.200
Increased Participation in Prevention Trials by Community Clinical Oncology Program	6.000
Intervention Study in Patients with Background of Colonic Polyps	1.000
Role of Folic Acid in Cancer Prevention	600
Stomach Center Prevention Trial	750
Increased Support for Clinical/Comprehensive Cancer Centers	15.000
Total, NCI	48.944

NHLBI	
A Randomized Trial to Study the Effect of Digitalis on Survival in Patients with Congestive Heart Failure	200
Antiarrhythmics and Beta-Blockers Study	2,000
Clinical Trial for Management of Elevated Blood Pressure in Children	2,300
Pilot Study of Treatment for Silent Myocardial Ischemia	1,950
Sleep Apnea Intervention Trial	2,070
Treatment of Idiopathic Fibrotic Lung Disease	1,000
Membrane-Active Agents to Prevent Sickle Cell Disease	500
A Randomized Prospective Study of Transfusion Therapy for Prevention of Recurrence of Stroke in Sickle Cell Disease	750
Childhood Asthma Intervention Study	1,782
Peripheral Vascular Disease	2,000
Total, NHLBI	14,552

UNFUNDED CLINICAL TRIALS: FY 1990 (Continued)

NIDR	FY 1990 Amount
Clinical Evaluation of the Intraoral Fluoride Releasing System for the Prevention of Dental Caries	$200
Effectiveness of Various Modalities of Fluoride Treatment Among Adults at High-Risk for Dental Caries and Gingivitis	600
Impact of Xylitol Chewing Gum as a Caries Preventive Strategy in Young Adults	200
Evaluation of Pit and Fissure Sealants for Disease Prevention for Small Carious Lesions in Adults	350
Chlorhexidine and Fluoride to Prevent Caries in Xerostomic Patients	1,200
Role of Coaggregation in Colonization of Veillonella on Oral Surfaces	150
Comparison of a Mechanical and a Chemotherapeutic Approach for Improving Periodontal Health in Adults	250
Long-term Efficacy of Regeneration Procedures in Periodontal Therapy and Maintenance	500
Effect of Periodontal Treatment on Insulin Requirements of Patients with Diabetic Periodontitis	250
Treatment of Advanced Stages of Periodontal Disease	100
Multi-Institutional Clinical Trial of Dental Implants	450
Use of Titanium Endosseous Implants in Special Populations	200
Clinical Assessment of New Bonding Technology	800
A New Improved Root Canal Material	1,200
Dental Cement Clinical Trials	1,200
Placement and Replacement of Dental Restorations	1,000
Effect of Drug Pretreatment of Individuals at Risk for Oral Cancer	450
Reduction of Oral Complications of Cancer Therapy	350
Effects of Drug Therapy on Recurrent Oral Cancer	500
Use of Oral Rinses of Tranexamic Acid in Patients Receiving Anticoagulant Therapy	125
Inhibition of Tumor Metastases by the Experimental Drug, SC-44463	200
CsA Therapy in Rheumatoid Arthritis	250
Factors that Trigger and Agents that Inhibit Reactivation of Herpes Simplex Virus	250
Developing Selective Potentiators of Opioid Analgesia	100
Orthognathic Surgery Clinical Trials	800
Total, NIDR	11,675

NIDDK	
Diet and Exercise in the Prevention and Treatment of Noninsulin-dependent Diabetes Mellitus	1,500
Clinical Study of Gallstone Recurrence Following Extracorporeal Shock-Wave Lithotripsy	500
Clinical Trial of Prevention and Therapy of Hypertensive Renal Disease in Black and Hispanic Populations	2,000
Clinical Trials in the Treatment of Primary Biliary Cirrhosis (PBC)	1,000
Comparison of Therapeutic Modalities in the Treatment of Interstitial Cystitis	1,000
Enzyme Replacement Therapy in Inherited Metabolic Diseases	1,000
Comparison of Amino Acid and Ketoacid Analogues to Essential Amino Acids as Nutritional Supplements for Protein Restricted Diets	2,000
Effective Weight Loss Strategies for Obese Diabetics in High Risk Minority Populations	1,500
Immunosupressants in Crohn's Disease	900

UNFUNDED CLINICAL TRIALS: FY 1990 (Continued)

NIDDK (Continued)	FY 1990 Amount
Immunotherapy for Pre-Type I Diabetics	$1,000
Liver Transplantation Trials Using Alpha Interferon PGE-1 in Severe Viral Hepatitis; Mabs to Prevent Reinfection in Hepatitis; and Salmon Calcitonin Liver Transplantation in PBC Patients	1,200
Use of Recombinant Human Erythropoietin in Adult and Pediatric Patients with Renal Failure	1,000
Alternatives to D-Pencillamine in Wilson's Disease	600
Assessment of Heme Arginate Therapy in Acute Porphyric Attacks	800
Effect of Diet on Lipid Levels in Diabetic Patients	800
Total, NIDDK	16,800
NINDS	
Study of Heparinoids for the Treatment of Stroke Prevention of Blood Clots)	2,145
Study of Surgical Treatment for the Management of Partial Seizures in Adults	800
Use of Total Lymph Node Radiation in Chronic-Progressive Multiple Sclerosis	1,000
Study of 3,4 Diaminopyridine in Multiple Sclerosis	136
Warfarin for Secondary Stroke Prevention	2,000
Excitatory Amino Acid Antagonist in the Treatment of Acute Stroke	400
Monocolonal Antibody Treatment of Multiple Sclerosis	500
Immunosuppresive Therapy of Exacerbating-Remitting Multiple Sclerosis	500
Efficacy Trial of a Calcium Channel Blocker in Patients with Partial Seizures	500
Clinical Trial of Copolymer I in the Treatment of Acute Optic Neuritis and Multiple Sclerosis	600
Study of Cyclosporin A for the Management of Myasthenia Gravis, and Guillain Barre Syndrome	525
Clinical Trial of a Benzodiazepine in the Treatment of Status Epilepticus	500
Evaluation of L-Dopa Modifiers in the Treatment of Parkinson's Disease	1,500
Total, NINDS	11,106
NIAID	
Efficacy Trial of Childhood Asthma	375
Efficacy Trial of Live, Attenuated, Quadravalent, Oral Rotavirus Vaccine	1,000
Efficacy Trial for Acellular Pertussis Vaccines	3,081
Efficacy Trial of Influenza A Vaccine	1,000
Efficacy Trial of Hib Conjugate Vaccines	2,414
Therapy for Neonatal Herpes	725
Efficacy Trial for Genital Herpes Vaccine	597
Hepatitis with Ribaviran	274
Total, NIAID	9,466
NICHD	
Phase I and II Clinical Trials of a New LHRH Antagonist for Male Fertility Regulation	500

UNFUNDED CLINICAL TRIALS: FY 1990 (Continued)

NICHD (Continued)	FY 1990 Amount
Pathophysiology and Prediction of Sudden Unexpected Infant Death	$3,000
Trial of Dichloroacetate (DCA) in Hyperlactic Acidemias of Childhood	375
Nutritional Intervention in High-Risk Pregnancy	450
Therapeutic Trial of Vitamin A in Prevention of Morbidity and Mortality from Bronchopulmonary Dysplasia (BPD) in Low-Birthweight Infants	375
Optimal Diet Composition for Infants of Low Birthweight	375
Prenatal Diagnosis Using Fetal Cells in Maternal Blood	500
Calcium Supplementation in Pregnancy for the Prevention of Hypertension, Preeclampsia, and Preterm Birth	600
Clinical Trial with a New Disposable Polyurethane Diaphragm with Spermicide Incorporated into the Matrix	150
Safety, Immunogenicity, and Efficacy of the NICHD Developed Pertussis Toxoid Vaccine in Infants in the United States	3,700
Safety and Efficacy of the NICHD Developed Pertussis Toxoid and Hib-Conj (H. Influenza Type b Conjugate Vaccine) in Infants in Sweden	750
Safety and Efficacy of the NICHD Developed Pertussis Toxoid in 18 Month Old Children in Sweden	800
Clinical Trials with S. aureus Vaccine in Infants in the United States	150
Clinical Trials with Group B Streptococcus Vaccine in Adults in the United States	450
Total, NICHD	12,175
NEI	
Glaucoma Prevention Trial	1,250
Thrombolysis in Central Vein Occlusion Study	2,600
Cryotherapy for Retinopathy of Prematurity Follow-Up Study	3,000
Endophthalmitis Vitrectomy Study	1,000
Vitrectomy for Trauma Study	1,500
Glaucoma Treatment Trial	800
Quality of Life Measurement in Glaucoma Treatment Study	1,150
Total, NEI	11,300
NIA	
Reducing Frailty and Injuries in Older People	3,500
Drugs and Biologicals for the Treatment of Symptoms of Alzheimer's Disease:	
--Nerve Growth Factor	500
--Huperzine	225
--Acetylcarnitine	1,000
--Milecemide	1,200
The Prevention of Delirium in the Demented Older Person: Development of Guidelines for Use of Common Medications	650

UNFUNDED CLINICAL TRIALS: FY 1990 (Continued)

NIA (continued)	FY 1990 Amount
Behavioral Management for the Secondary Symptoms of Alzheimer's Disease	$650
Tests on Biopterin Supplements in Alzheimer's Subgroup with Evidence of Biopterin Deficiency and or Drugs for Early Treatment of AD	1,000
Social and Behavioral Interventions for Reducing Burdens of Care for Alzheimer's Patients and Their Families	2,500
Cognitive Interventions to Improve Intellectual Functioning	1,500
Psychosocial Interventions for Improving Work Environments for Older Workers	1,000
Total, NIA	13,725
NIAMS	
Efficacy of 13-cis Retinoic Acid and Other Retinoid Derivatives in the Treatment of Keratinizing Disorders	1,000
Efficacy of Sulfasalazine in the Treatment of Reactive Arthritis	375
Use of Retinoids in the Treatment of Psoriatic Arthritis	500
Safety and Efficacy of 4-Hydroxyphenylretinamide in Patients with Rheumatoid Arthritis	1,500
Safety and Efficacy of Human Calcitonin in Treatment of Osteoporosis	1,000
Safety and Efficacy of D-Penicillamine Therapy for Systemic Sclerosis (Scleroderma)	1,200
Treatment of the Late Stages of Lyme Disease	500
Treatment of Erythema Chronica Migrans	1,000
Combination Therapies for Rheumatoid Arthritis and Systemic Lupus Erythematosus	600
Cyclosporin A in the Treatment of Severe Psoriasis	1,000
Total, NIAMS	8,675
NIDCD	
Perilymph Fistula: Controversial Treatment Strategies	1,200
Speech-Language Acquisition and the Deaf Child: Hearing Aids, Tactile Aids and Cochlear Implants	900
Taste Disorders: Zinc Compound Treatments	500
Total, NIDCD	2,600
NCNR	
Beneficial Outcomes for Low Birthweight Infants with Advanced Nursing Care Techniques	600
Total, NCNR	600
TOTAL, MAJOR NEW IN FY 1990, UNFUNDED	161,618

MAJOR NEW CLINICAL TRIALS READY TO BEGIN IN FY 1990
IF FUNDS WERE AVAILABLE

AIDS

	FY 1990 Amount
NHLBI	
Clinical Trial on Lung Pentamidine Toxicity	$2,000
Clinical Trial on Use of Pentamidine in Prophylaxis PCP	2,000
Use of Erythropoetin in Autologous Transfusions	1,404
Total, NHLBI	5,404
NIDR	
Prevention and Control of Oral Manifestations of AIDS	1,125
Characterization of the Immune Status of HIV-Infected Patients	667
MTP Treatment of AIDS Patients	150
Total, NIDR	1,942
NICHD	
Evaluation of New Condoms	600
NICHD AIDS Clinical Trials of New Treatments for Children with HIV Infection	14,500
Total, NICHD	15,100
NIAMS	
AZT in the Treatment of Skin Diseases in HIV-Positive Individuals	500
Total, NIAMS	500
TOTAL, MAJOR NEW IN FY 1990, UNFUNDED	22,946
TOTAL, NON-AIDS AND AIDS CLINICAL TRIALS IN FY 1990 UNFUNDED	184,564

FTES

Question. Dr. Wyngaarden, what was the NIH original request for FTE's? How many have been allocated in the President's Budget?

Answer. The original FY 1990 request for FTEs was 14,323, of which 13,200 were for non-AIDS activities and 1,123 were for AIDS. The FY 1990 President's Budget requests a total of 13,214 FTEs, of which 12,327 are for non-AIDS and 887 are for AIDS.

CLINICAL RESEARCH CENTERS

Question. Dr. Wyngaarden, I have heard from researchers in Pennsylvania that the NIH extramural clinical research centers continue to be underfunded. Dr. Engleman, from the University of Pennsylvania, contacted my office particularly concerned about the proposed funding for FY 1990. How much is included in the FY 1990 budget for clinical research centers? How does that compare to FY 1989? How much would the NIH need to maintain a current services budget for this program? How much would the NIH need to fund these centers at their fully approved levels?

Answer. The FY 1990 President's Budget (excluding AIDS) includes $552 million for research centers, of which $93 million is specifically for general clinical research centers. This compares to $544 million for research centers of which $90 million is for general clinical research centers in FY 1989. To maintain a current services budget in FY 1990, NIH would need $566 million for research centers, including $95 million for general clinical research centers. To fund the centers at their fully approved FY 1990 levels, $671 million would be needed for research centers, of which $116 million is for the general clinical research centers.

ADVISORY COMMITTEE ON WOMEN'S HEALTH

Question. Dr. Wyngaarden, does the NIH have an NIH Advisory Committee on Women's Health Issues? What is the purpose of this Committee? How often does it meet? Has this Committee made any recommendations or reports that might be of particular interest to the members of this subcommittee?

Answer. The NIH does have an NIH Advisory Committee on Women's Health Issues. It was established, as were comparable advisory committees or task forces in the other components of the Public Health Service, to insure that the relevant recommendations of the Task Force on Women's Health Issues are implemented. The former Task Force, replaced by the PHS Coordinating Committee on Women's Health Issues, is monitoring implementation of the recommendations on a PHS-wide basis. The NIH Advisory Committee established in 1985 has been holding meetings about once a month since its inception. In the current fiscal year the meetings have been bimonthly. The Committee has developed a report that is in its final draft form and that contains a number of recommendations on women's health issues.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

BUDGET REDUCTION

Question. Dr. Wyngaarden, due to certain restrictions imposed on the Congress by the Gramm-Rudman-Hollings legislation and the need to allocate a limited amount of dollars, an across-the-board cut has been imposed on all discretionary programs under this Committee's jurisdiction for the last two years. Last year the cut was approximately 1.2 percent. How are these across-the-board cuts implemented by the NIH?

Answer. The across-the-board reductions included by the Committee in the appropriations bill are taken, as directed, against each program, project and activity indicated by the Committee. Within each program, project and activity, the individual Institutes have some discretion as to how the reductions will be distributed, taking into account, for example, research opportunities and program balance.

Question. Is there an NIH-wide policy for implementing these cuts? I would be particularly interested in how the cuts were made in the Division of Research Resources?

Answer. Other than the requirement to take reductions by program, project and activity, there is no NIH-wide policy for implementing these cuts. In the case of the Division of Research Resources, the FY 1989 reduction was applied to all their research and resource activities.

NATIONAL CANCER INSTITUTE

STATEMENT OF DR. SAMUEL BRODER, DIRECTOR

BUDGET REQUEST

Senator HARKIN. Dr. Wyngaarden, I would like to go on to the next panel and hear from them. We have them lined up. First is the Director of the Cancer Institute; then the Directors of the Allergy, Neurological, and Deafness Institutes, and the Directors of General Medical Sciences and the National Library of Medicine.

Dr. Wyngaarden, if we could, we will just have each of the Institute Directors make a very brief statement. I am sure we will have a few questions. We will do it institute by institute and just go down the line. Even though there may be some overlaps, we can come back to those.

If we could, we will start with Dr. Broder, the Director of the National Cancer Institute, which is requesting $1.646 billion, which is a 4.8 percent increase over last year.

Again, to repeat what has been said before, and I will talk about this again, AIDS funding is proposed to grow 24 percent, while the non-AIDS and cancer request will grow 3.2 percent.

I want to make that point and we will come back to it later.

PREPARED STATEMENT

Dr. Broder, welcome to the subcommittee. If you would make a brief statement, we would appreciate it.

Your whole statement will be put into the record.

[The statement follows:]

STATEMENT OF DR. SAMUEL BRODER

This is my first opportunity to testify before the Congress since being sworn-in as Director of the National Cancer Institute (NCI).

The momentum of cancer research has increased over the past few years; and we now have before us the following accomplishments:

- Significant developments in the science and application of cancer prevention and early detection. We will give high priority to research in these areas and their subsequent applications.

- An understanding of the genetic and molecular basis for cancer, including the identification of broad families of genes that accelerate (so-called oncogenes) or retard (so-called suppressor genes) the development of cancer.

- The characterization of physiologic growth factors and their receptors, which when expressed at the wrong time and in the wrong place, contribute to the development of cancer. During the past year we took advantage of this knowledge to develop a new treatment for widely-spread prostate cancer using a drug called suramin. This drug specifically inhibits a class of growth factors that stimulate the development of prostate tumors. This approach is being expanded to treatment of other types of solid tumors and leukemias.

- The elucidation of new families of viruses, such as the human retroviruses involved in AIDS and some leukemias. The long-term commitment of NCI to the study of such viruses has contributed to many of our successes in preventing and treating AIDS. Such viruses are involved in certain chronic liver and neurologic diseases, so the value of this research extends beyond cancer.

- An understanding of the ways that cells evade the effects of cancer drugs and consequent methods to reduce drug resistance and improve therapies.

- A better understanding of natural biological substances and their potential applications. This has led, for instance, to using the patient's own host defense cells, appropriately activated and multiplied, to shrink tumor cells.

- Increased expertise in using monoclonal antibodies and genetically-engineered products to treat patients with advanced cancer and AIDS.

- Improved adjuvant therapy. Successful adjuvant trials in breast cancer, colo-rectal cancer, osteosarcoma, pediatric sarcomas, and extremity soft tissue sarcomas have extended the value of chemotherapy when added to surgery and radiation.

- The use of the latest supercomputer technology, employing concepts from physics and chemistry, to understand how cancer cells

and the AIDS virus function and then to design new strategies to treat these diseases.

The good news is that many thousands of lives have been saved by virtue of these and other accomplishments of the National Cancer Program, but we still face formidable problems. As a physician I have been taught to give both the good and the bad news when discussing diseases. Sadly, there still is bad news. As yet, we still do not have a complete set of molecular explanations for cancer. Cancer treatments are not able to heal every cancer patient. Moreover, even our most certain knowledge is not always taken to heart. For instance, we know that smoking contributes to approximately one-third of all cancer deaths in this country. Moreover, I am concerned that blacks suffer a disproportionate burden of cancer incidence and mortality in our country.

First, and foremost, any commitment to defeat cancer, is a commitment to support investigator-initiated basic research through the research project grants program of the Institute.

Our current knowledge about oncogenes is a direct outcome of such basic research. Today we can count 40 oncogenes, genes that when mutated, overexpressed or improperly regulated lead to cancer.

In the past two years, information about suppressor genes or anti-oncogenes has continued to emerge from our basic laboratory research. Certain tumors develop because genes that would suppress them are lost or inactivated, using a "two-hit" process. These suppressor genes are important in certain rare inherited cancers, such as a cancer of the eye, but they play a role in many common tumors as well. Eventually it may be possible to replace a suppressor gene, or a relevant product, if one is needed to keep a tumor from developing.

Our research has identified various substances associated with cancer in humans, starting of course, with cigarette smoke in smokers, side-stream smoke in non-smokers, carcinogens in chewing tobacco, several occupational and environmental agents, certain types of viruses and dietary factors. Practical information continues to emerge about various nutrients or components of food, such as excess intake of dietary fat which may either accelerate or inhibit the development of cancer. A recent study suggests that vegetables in the allium family, such as garlic, onions, and scallions, may protect against cancer of the stomach. Research such as this will eventually provide information to guide the public and the food industry. The NCI has excellent collaboration in its nutrition program with the U.S. Department of Agriculture which provides a foundation for future research.

We are continuing to study the interactive effects of substances such as cigarette smoke and radon, particularly in relationship to lung cancer. Furthermore, there has been progress in understanding the genetic changes that may occur in normal cells as a prelude to the development of lung cancer. Studies suggest that at least two oncogenes and one or more suppressor genes are implicated in this process. These leads may eventually help us to identify individuals for whom special preventive interventions or early therapy would lead to more effective control of cancer.

We are studying a number of chemopreventive agents to determine whether the addition of synthetic or natural nutrient supplements to the diet can lower cancer incidence. A partial list of agents being studied includes folic acid, vitamin B12, retinoic acids, beta carotene, vitamin C, and vitamin E.

NCI is planning to expand the basic research capacity of its intramural program in cancer prevention and nutrition studies as a way of stimulating more basic research in this area.

Application of both established and new technology will facilitate the early diagnosis of cancer. For example, more widespread utilization of mammography in appropriate age groups could reduce breast cancer deaths significantly.

The past year has seen a number of diagnostic and treatment techniques develop directly from basic laboratory research. One, a new painless urine test for bladder cancer, detects a specific protein, autocrine motility factor. Another test may detect lung cancer years before the disease is visible by x-ray. Both of these new experimental approaches must be proven in confirmatory studies, but offer the possibility that diagnosis of these cancers will be made at an early, more treatable stage.

Therapy research has been and will remain a high priority. We will build on the earlier NCI foundation making it possible to cure certain advanced cancers by chemotherapy and/or radiation, including certain leukemias, lymphomas, testicular tumors, and gynecologic cancers. We are continuing to apply the knowledge gained from basic research to new therapeutic strategies.

Central to treatment research is the development and marketing of effective anti-cancer drugs. The NCI maintains a large-scale screening system for both natural and synthetic products in test-tube assays of anti-tumor activity. Approximately five drugs per year are developed by NCI scientists as experimental agents from these screening system. NCI studies have brought several drugs to Food and Drug Administration (FDA) approval during the last year. These include drugs such as flutamide, carboplatin, and ifosfamide/mesna. We will continue to work with the FDA to develop new drugs quickly and to avoid unnecessary regulatory barriers.

Experience with the biological response modifiers such as colony stimulating factors and interleukin-2, is continuing to grow at a rapid rate. New combinations of such biological response modifiers are being tried and the successes to date, particularly in previously intractable malignancies such as cancer of the kidney and melanoma, are encouraging. Significant responses have been observed using alpha-interferon and chemotherapy together in multiple myeloma, a result not seen with chemotherapy alone.

We are continuing our exploration of adoptive cellular therapy in which a patient's own host defense cells are removed from the body, multiplied, activated, and reinfused into the patient. Impressive results are being obtained in otherwise untreatable tumors, such as was the case in a recent study which produced tumor regression in 60 percent of 20 patients with advanced malignant

melanoma. While these are preliminary results, they point the way to new effective therapies in the future.

In mid-January, the NIH and the FDA approved a proposal by NCI and National Heart, Lung, and Blood investigators to transfer a foreign gene into host defense cells. As this technology develops, it may eventually be possible to enhance the clinical value of this adoptive cellular therapeutic approach by selecting and inserting genes that potentiate the tumor-killing properties of the host defense cells.

NCI scientists have made progress in combining chemotherapy with new intensive regimens of radiation therapy. Thus, the use of two anti-tumor drugs, VP-16 and cis-platinum, together with a twice daily regimen of radiation therapy has significantly improved the survival of patients with certain lung tumors that are still confined to the chest cavity, but not removable by surgery. The four-year overall survival is nearly 60 percent, compared to approximately 10 to 20 percent with the best previous therapies. NCI will continue to pioneer research on adjuvant therapy, using drugs in addition to surgery and/or radiation to treat residual cancer when it is still in a microscopic form. Recent adjuvant clinical trials in which patients receive post-operative chemotherapy or hormonal treatment have shown slowing of recurrence of breast cancer after initial surgery regardless of whether the patient has positive or negative axillary nodes at time of surgery.

Moreover, encouraging results are being obtained in patients after removal of colon cancer. In patients at high risk of recurrence, adjuvant treatment following surgery appears to delay recurrence and also prolong survival. Because colon cancer is so common, this improved outcome is encouraging, indeed. The major advances cited in breast and colon cancers have come out of NCI-funded clinical trials by clinical cooperative groups, made up of university groups and community physicians which have banded together for the purpose of accruing patients to clinical trials.

Last year, NCI initiated a mass-mailed "clinical alert" to inform practicing physicians about the new data derived from clinical trials regarding the benefit of adjuvant treatment in very early breast cancer. The clinical alert was predicated on the judgment that a delay in communication of even a few months could result in a less favorable outcome for thousands of women with breast cancer. A follow-up inquiry of physicians who received the alert revealed that a significant percentage indicated that they would change their therapeutic practice for the relevant breast cancer patients.

NCI will continue to maintain and support the Surveillance, Epidemiology and End Results (SEER) program. SEER is a major statistical tool for determining cancer incidence, trends, and impacts of new diagnostic and therapeutic technologies. NCI plans to add registries to the SEER program which will improve its coverage of black and Hispanic population groups.

NCI will remain active in translating information into action. A comprehensive program includes a network of trained specialists, 60 cancer centers of various types, a cooperative clinical trials

program, community oncology programs, outreach activities, the International Cancer Information Center, which includes the computerized database Physician Data Query (PDQ), the toll-free nationwide Cancer Information Service (CIS), as well as a major cancer prevention awareness program. In addition, NCI's Office of Cancer Communications provides the public with information needed to make sound choices about smoking, diet, diagnosis, and treatment.

The NCI has a strong commitment to the fight against AIDS and its related disorders. An NCI task force coordinates and applies resources, cutting across traditional organizational boundaries, to accelerate the development of an AIDS vaccine.

Moreover, a number of new therapies discovered and originated by NCI scientists have made their way to clinical trials. The most widely known is AZT, but a number of other drugs are being tested. A broad family of nucleoside analogues, called dideoxynucleosides such as ddC and ddI, are now in large-scale testing. Preliminary results indicate that these agents may stop AIDS virus replication in patients. In addition, in collaboration with the private sector, certain genetically-engineered agents, such as GM-CSF which stimulates the bone marrow, and CD4, which is a protein substance that can bind to the AIDS virus, are being tested in NCI-sponsored trials. This work is important on scientific grounds because of the new knowledge gained; humanitarian grounds because these therapies are likely to prolong survival and alleviate suffering; and on economic grounds because the NCI, and the NIH as a whole, is a major force for encouraging competition in product development.

As newer treatments for AIDS extend lives, there will be a need to treat the cancers that frequently complicate AIDS. This is already the case, to some extent, as NCI scientists have found in the last year several novel factors which affect the growth and development of Kaposi's sarcoma. A search for specific inhibitors which might be adapted for clinical use has been initiated.

In summary, we take some measure of satisfaction in the progress that has been made in cancer prevention, early diagnosis, and therapy, as well as in the advances and expansion of knowledge that has occurred in our understanding of cancer through basic research. At the same time, we must be aware that there is still much remaining to be done. The good news must be tempered by the sober reality that some forms of cancer are still untreatable, and some others, while treatable, are not curable with the available knowledge. The challenge remains formidable and compelling. I believe that we can meet this challenge. Mr. Chairman, the FY 1990 budget request for this Institute is $1,494,741,000. I will be happy to answer any questions you may have.

OPENING REMARKS

Dr. BRODER. Thank you very much, Mr. Chairman. I am very pleased to be here to testify for the first time as the Director of the National Cancer Institute.

I am submitting my full remarks for the record. I am also submitting a descriptive booklet summarizing certain achievements and accomplishments of the Institute during the previous year for your perusal and for the other Members.

Mr. Chairman, the primary mission of the National Cancer Institute is to prevent and cure cancer. The foundation stones for this effort include basic research, clinical trials, both in prevention and treatment, and our Cancer Centers Program.

All three foundation stones are necessary to support our overall effort and to insure its success.

Moreover, a number of educational activities accompany every aspect of our efforts.

Since the passage of the National Cancer Act in 1971, we have seen an explosion in our understanding of the molecular and biological features of cancer. Some of this knowledge has had and will continue to have direct application in many other diseases, including AIDS.

The sum total of the National Cancer Program has led to progress against cancer for individuals under the age of 65, and we can see a significant reduction in the annual death rate for a wide range of common cancers since 1973 in that age group.

Moreover, we have improved the quality of life for cancer patients in many ways that are not reflected in the cancer death rate statistics per se. But the news is not always good.

For individuals over the age of 65, we have not made as much progress. Moreover, blacks and certain other minorities bear a disproportionate burden of death from cancer. Even our most certain knowledge, for example, with respect to smoking, is sometimes not taken to heart.

I am very sorry to say that in this particular year, we expect that breast cancer will fall behind lung cancer as a major cause of death in women. Lung cancer will overtake breast cancer as a cause of cancer deaths, according to our projections this year, and this is related to smoking practices in women.

It may also be worth stressing that many of the activities initiated and supported by the National Cancer Institute have had profound implications for the vitality and competitiveness of American biotechnology enterprises, and we will continue to work with ethical pharmaceutical companies and biotechnology industries to achieve our mission and ensure rapid technology transfer to the public, and to ensure product competition.

In summary, we take some measure of satisfaction in the progress that has been made in cancer prevention, early diagnosis and therapy, as well as in the expansion of knowledge that has occurred in our understanding of cancer through basic research. Yet, this satisfaction must be tempered by the sober reality that some forms of cancer are still not treatable and others, while treatable, are still not curable.

The challenge remains formidable and compelling, but I believe we can meet this challenge.

Mr. Chairman, the fiscal year 1990 budget request for this Institute for cancer research is $1,494,741,000.

I will be very pleased indeed to answer any questions you may have.

HUMAN GENOME PROJECT

Senator HARKIN. Dr. Broder, thank you very much for that concise statement for the record.

Let me just ask one thing, sort of out of order here.

You say here that we now have before us the following accomplishments: An understanding of the genetic and molecular basis for cancer, including the identification of broad families of genes that accelerate or retard the development of cancer.

Back to the human genome project, does this project have a lot of bearing on this, in other words, understanding and mapping out the human genome?

Dr. BRODER. Yes, sir; I believe it will.

Many of the technologies supported and accelerated by the National Cancer Institute over the last 17 or 18 years have made possible much of the technology that will now go into the genome project. We expect that, in turn, we will receive significant dividends in understanding how oncogenes, cancer causing genes, work, what goes wrong and when it goes wrong. In addition, there is an entirely new family of genes, called suppressor, or anti-oncogenes, whose job is to prevent cancer in a cell. When they malfunction due to multi-hit phenomena, a cancer may occur.

So we believe that there will be significant advances in many directions.

CANCER DEATH RATES

Senator HARKIN. Let me talk a little bit about the cancer death rates. This is from U.S. News and World Reports.

It says that since 1974, the 5-year survival rate has increased less than 1 percent and is actually declining for some major forms of cancer. Also, the overall rate at which cancer patients die has been largely unchanged since the mid-1970's.

Indeed, the Cancer Institute reported a new piece of troubling data. The most recent statistics on breast cancer for 1983 and 1984—and I don't know if there are any more recent statistics than for 1983 and 1984; there may be now—show an unexplained rise in the rate at which young, white women were dying from the disease, reversing a decade-long trend toward lower breast cancer mortality in young women.

Equally worrisome, the overall rate of cancer, even when adjusted for the increasing age of the population, has been rising at about 1 percent a year for 30 years.

This is all data I guess from the Institute itself.

How do you respond to these kinds of concerns, that the 5-year survival rate has increased less than 1 percent and is declining for some cancers? The overall rate is increasing, even when adjusted for age.

Are these basically true statements?

Dr. BRODER. Sir, I think it depends on how one looks at the statistics in the booklet which is in your hands. There is a breakdown of data in your booklet. I think one has to look at where progress has been made and where progress has not been made or has not been made to the same extent.

If you look at individuals who develop cancer under the age of 65, for a variety of major malignancies, in my opinion, there is no question but that there has been a drop in the annual death rate, that is, the number of deaths per 100,000. In colo-rectal cancer, since 1973, for individuals under the age of 65, there has been a drop of 14 percent in the annual death rate. For ovarian cancer, it is 24 percent; for stomach cancer, a drop of 25 percent; for bladder cancer, a drop of 30 percent; for cancer of the main portion of the uterus, a drop of 30 percent; for the cervical region of the uterus, a drop of 40 percent. These are common tumors.

Senator HARKIN. Are these 5-year survival rates that you are giving us?

Dr. BRODER. I'm giving you death rates, that is, the number of people who die per year per 100,000. For those people under the age of 65, for some common tumors, there has been a drop.

In addition, if you pick some interesting but not as common tumors, such as Hodgkin's disease, there has been a 50 percent drop in the annual death rate per 100,000; and for testicular cancer, a dramatic 60 percent reduction in death rate.

Where we have not made as much progress is in individuals over the age of 65. There we need to do more.

Lung cancer, which we believe in many cases or in the high percentage of cases, perhaps 80 to 90 percent, is a preventible kind of cancer, is driving many of the statistics that you see.

In addition, we are seeing a disparity in the death rate for minorities. In fact, that disparity is being fueled by the progress that is being made in the average white American. We are seeing a drop in the death rate for several different categories of tumors, at the same time that there is a rise for black Americans and other minorities. That is true for colo-rectal cancer, head and neck tumors, and so on.

Senator HARKIN. How do you respond to the charge that most of these advances occurred primarily between 1960 and 1974, but that not much has happened since that time?

Dr. BRODER. Sir, I have deliberately given you the figures since 1973. The comparative figures that I have just given you are from 1973 compared to 1986. I did not go back before that time to give you the figures in the under age 65 group.

Senator HARKIN. This is since 1973?

Dr. BRODER. Since 1973.

If I went back to the mid-1960's or mid-1950's, I would give you more impressive gains. But I feel that that would not be a fair reflection or yarkstick for you to consider.

The Cancer Act was passed in 1971. So I feel that 1973 is an appropriate baseline for comparison.

PROGRESS IN THE WAR ON CANCER

Senator HARKIN. Let me try something else here then, and these are good responses.

In 1971, when President Nixon declared war on cancer, an estimated 335,000 people died that year of cancer.

In 1989, $16 billion later in National Cancer Institute spending, it is estimated that 502,000 people will die of cancer this year.

Dr. BRODER. We believe those figures are accurate. My entire theme, my text and subtext in testifying here before you is that there is good news and bad news. Where we identify bad news, we must state it and try to solve it.

But, at the same time, the bad news should not overshadow or nullify the accomplishments which have been made.

There is no question in my mind that for individuals under the age of 65, as a result of a combination of prevention, early diagnosis and better treatment, we have made progress against a number of both common and uncommon tumors.

In individuals over the age of 65, due to a number of factors which might relate to less than optimal early diagnosis, less than optimal prevention, and perhaps suboptimal treatment interventions, we have not made as much progress.

I have directed all of the divisions of the Cancer Institute to address this specific issue of death rate of individuals over the age of 65. In addition, I have directed all aspects of the Cancer Institute to attempt to address the issue of the increasing differential death rate in blacks and other minorities, which I find unacceptable, and every predecessor in the Cancer Institute who has served before me as Director has found unacceptable.

POVERTY AND CANCER

Senator HARKIN. I had a question about that.

Are there any reasons that blacks have a higher death rate from these types of cancer, other than lifestyle, availability of good medical care? Is that the primary reason?

Dr. BRODER. We think that, to a large extent, the differential death rate, burden of death and incidence from cancer, is, in part, a reflection of the imprint of poverty and access to the system.

We will do what we can to resolve this issue.

Senator HARKIN. Why would you get cancer if you are poor, rather than wealthier? What is the difference? Is it diet?

Dr. BRODER. Sir, I believe that cancer is one of the consequences of being poor.

Senator HARKIN. Is it diet?

Dr. BRODER. Diets, yes. Also certain types of behavior—for example, smoking—and to some extent the combination of smoking and drinking.

Senator HARKIN. Lack of complete checkups?

Dr. BRODER. The inability either to gain access or the unwillingness to make a priority for early diagnosis and lack of state-of-the-art care.

In addition, I believe that in some inner-city neighborhoods, it is difficult for people to make health prevention a priority because of the other exigencies and realities of the life that they must lead.

CANCER CENTERS

Senator HARKIN. Let me ask you about the cancer centers, if I might just skip around a bit.

Your budget shows there is a $1.2 million reduction in your cancer center line item, although you show funding for 60 centers next year, the same number as were funded in 1989. I understand that 17 centers are up for renewal.

Is it accurate to say that it is expected you will lose five to seven centers based on the current funding level request?

Dr. BRODER. In order to meet the funding realities that we face, we expect four or five centers will lose their core grant support in this fiscal year 1989, and we expect a comparable number in turn will lose core grant support in 1990.

This is a decision which was made in consultation with all parties that are interested. We are funding cancer centers when they come in as type 2 recompetitions, or when they come in for their first initial review at 85 percent of recommended levels.

It is very difficult for us to go below 85 percent without, in effect, nullifying the peer review recommendation process. In order to meet those realities and not go below 85 percent, certain centers will have to lose their core grant support in order for us to maintain a funding pattern for other centers to function and to function with the vitality that we need.

Senator HARKIN. So you're going to lose some, then.

Dr. BRODER. We predict that we will lose four to five centers in 1989 and that we will lose roughly five centers—they will lose their core grant support in 1990.

Senator HARKIN. Tell me about the impact of that.

Dr. BRODER. The impact will be that we will have significant challenges in our program.

Senator HARKIN. Are these centers doing good research?

Dr. BRODER. These centers are exceedingly important.

The three major priorities of the Cancer Institute are basic research, clinical trials, and prevention and treatment, and our Cancer Centers Program. They are an important component, particularly the comprehensive cancer centers, in disseminating information, transferring technology, helping early diagnosis, teaching prevention, and introducing state-of-the-art treatments to communities.

So I think communities that lose cancer centers will feel the effect.

CANCER TREATMENT IN RURAL AREAS

Senator HARKIN. That is one thing that I would ask Senator Bumpers on this. They are losing these centers in the budget, but I understand from the GAO report that only one-third of the doctors across the country are using state-of-the-art cancer treatment techniques.

One of the things that you said was that the centers are so important for disseminating this kind of information.

So, if you defund or if some of the centers have to close down, then we can expect that the one-third would probably even increase.

A lot of doctors in rural areas, for example, do not really have that kind of knowledge and rely upon these centers to get that kind of information out so they can have readily available state-of-the-art types of treatment techniques.

We could expect that number maybe to increase, the number of one-third of the doctors, who are using it. I'm sorry, it would be less than that, if these centers go out of existence.

Would that be a fair statement?

Dr. BRODER. I would not disagree with your assessment.

Senator HARKIN. Well, that bothers me. I mean, we have enough problems in the rural areas and small towns, with doctors trying to treat patients. If they can't get that kind of information, that really bothers me.

TECHNOLOGY TRANSFER

I have just one last question.

I understand that from the point of a researcher, having a new idea about a treatment or drug, to the time it takes to be available for use is about 10 years, and before it is generally used widely by practicing physicians, it takes almost 15 years.

Are you satisfied with this pace of implementing new and exciting ideas about the treatment of cancer in the general practice, and is there any way of shortening that time period?

Dr. BRODER. Sir, I am not satisfied. It is a factor in my high blood pressure. [General laughter.]

Senator HARKIN. Why does it take so long? Is there anything we can do to collapse that timeframe? Is there anything that we can do to help here? I don't know, maybe there is. But I just don't know.

Dr. BRODER. I think there are a number of things which we have done and will continue to do. One thing is that we will continue to try to use our cancer centers program to help transfer technology and to ensure that communities that they serve are made aware and are implementing the latest technologies that we have in prevention, early diagnosis, and treatment.

Another area is that we will try, insofar as we can, to disseminate knowledge according to our best interpretation of when knowledge must be disseminated, but not necessarily wait for publication of knowledge resulting from clinical trials.

It sometimes takes 1 year or more for a paper to undergo the review process that leads to formal publication.

My predecessor, Dr. DeVita, issued a clinical alert in the matter of a new treatment for certain forms of breast cancer. He did a direct mailing to physicians in a variety of settings, revealing information in the clinical trial that subsequently was published 9 months after the mailing. So doctors were able to begin implementing a new kind of treatment or treatment philosophy without experiencing the usual delays.

I believe that that decision was correct then, and I believe that such decisions would be correct now.

Senator HARKIN. Senator Bumpers, do you have questions on the Cancer Institute?

Senator BUMPERS. Thank you.

Dr. Broder, I take it from this U.S. Department of Public Health publication on breast cancer that there are some States here—the District of Columbia, New Jersey, New York, Delaware, and Illinois—where both the pre- and post-menopausal incidence of cancer is much higher in both cases than in other States.

Do you know of any environmental reason? Do you have any opinion as to the environmental reason for that?

Dr. BRODER. The causes of breast cancer are not always clear. But we think that some of the issues that will affect the mortality figures that one sees in breast cancer, which is not precisely what you have asked because you have asked about incidence figures, but the net outcome of the——

Senator BUMPERS. I take that back. These are deaths.

Dr. BRODER. The mortality figures then will reflect whether women in the regions you mentioned are availing themselves of the best technology. We know that mammograms, which we believe should be offered to women annually or at least every other year following the age of 40, and at least annually following the age of 50, can have a dramatic impact on mortality due to breast cancer, and perhaps could reduce the amount of breast cancer deaths by a third.

Now, that technology is only good if individuals will use the technology.

We are trying to explore new ways of reaching populations with these newer techniques of early diagnosis, and we are also trying to work with State health agencies and with the District of Columbia, through the Division of Cancer Prevention and Control.

I have personally met with Dr. Reed Tuckson to try to see what we can do to reverse some of the statistics in the District of Columbia involving breast cancer and other diseases as well.

I think that we need to ensure that our Cancer Information Service, which is a major mechanism that allows individuals to get information, is widely utilized. We have a toll free number; one can dial the number 1-800, and then the number 4 and then the digits for "Cancer" 1-800-4-CANCER. One can reach a trained person who will speak about state-of-the-art treatment for a specific cancer.

We also need to make sure that doctors are using the treatment modalities that we have.

We now know that it is not a good idea for a doctor to wait for a cancer to come back; that in many situations, if not in a majority of situations, it is best to begin certain treatments, following the initial operation for breast cancer, so that the tumor can be treated while it is still in microscopic form, when the maximum advantage can be gained by treating early.

These are the kinds of information we are trying to disseminate. We are hoping that we can get the cooperation of all members of the academic and practicing communities.

IMPROVED DIAGNOSTIC TECHNIQUES

Senator BUMPERS. These figures that you gave a moment ago about the improved mortality rates in certain kinds of cancer, is that due mostly to earlier diagnosis? I don't know when the colonoscopy technique was developed, but obviously you could virtually eliminate colon cancers in this countries if everybody had a colonoscopy every couple of years.

Is that a fair statement?

Dr. BRODER. Sir, it is scientifically correct.

It is true that if everyone had a colonoscopy every year and had early polyps removed, that would lead eventually to an astonishingly dramatic reduction in the colon cancer death rates in this country. But that is not a recommendation that has been made, however, nor am I making it to you at this time because there would be a number of factors suggesting that that would not be the most cost-effective approach to this problem, at least at this time.

But your statement, just in isolation, is correct.

Senator BUMPERS. So a lot of these dramatic figures on mortality rates are because, for example, of mammography and colonoscopies and so on, which are new and fairly advanced diagnostic tools that we have that we did not have previously.

CHEMOTHERAPY

Do we have any instances of where a metastacized cancer has been cured with chemotherapy?

Dr. BRODER. Yes, sir.

There are a number of tumors which can be cured, even in metastatic form. Certain forms of testicular cancer, for example, which used to be uniformly fatal in young men, can be cured with an astonishingly high rate. Certain types of lymphomas, Hodgkin's disease, and so on, can be cured with a high frequency. Certain types of childhood leukemias, which were uniformly fatal within the lifetime of most people in this room, can now be cured in a high percentage of cases.

But, having given you the good news, I do want to temper it with the bad news, which is that for many advanced visceral malignancies, we do not have a technology for cure, and that is why we need to redouble our efforts.

I would comment in response to your question that much of the improvement of annual death rates that we see in certain tumors is, in fact, related to prevention technologies, to sounder diets, and, in particular, to certain things that are not high grade technology.

For example, white men in this country have had a significant reduction in the amount of smoking that they do. We have made progress in that.

However, we are not making progress in certain minority groups, and I am sorry to say that we are not making as much progress in women.

WOMEN AND LUNG CANCER

Senator BUMPERS. Is that what those lung cancer statistics indicate among white women?

Dr. BRODER. Sir, that is correct.

Senator BUMPERS. That their smoking habits have not changed that dramatically?

Dr. BRODER. They have not changed that dramatically.

But, in addition, women, unfortunately, are now reaping a harvest of smoking that was sown in previous years. These projections are very disturbing to me.

I do believe that we will have lung cancer surpass breast cancer this year as a cause of cancer death among women. If it does not do it this year, it certainly will do so in the near future.

CENTERS

Senator BUMPERS. Dr. Broder, what would it cost us to get back to the 60 core centers that we had in 1980?

Dr. BRODER. To get back to a complement of 60 core support grants for our Cancer Centers Program, we would need approximately $5 million to $6 million this year, and roughly speaking, an additional $5 million in fiscal year 1990, for an approximate total figure of $10 to $11 million by fiscal year 1990 to maintain the 60 core grants for our cancer centers.

COMPUTERIZED DATABASE FOR TREATMENT METHODS

Senator BUMPERS. My final question touches on what both you and Senator Harkin mentioned earlier.

We have a tendency to personalize, but I am reluctant to do so, and I don't think I have ever done this in public before.

My daughter had a spinal cord tumor diagnosed when she was 2 years old, and we had a big debate in the medical community where she was about what the treatment ought to be.

Interestingly enough, Betty and I wound up just making personal phone calls all over the United States about whether she should be radiated or whether there was a potential for surgery or what.

We finally found a doctor at Children's Hospital in Boston who had seen three cases like it, and he operated on her, and she was 4 years old at the time he operated. She is a very happy, healthy, bright, 27-year-old daughter now.

It was a benign astrocytoma, but a very extensive one. But I was amazed. We called six different university centers and got essentially six different answers, and every one of them prescribed radiation to some extent, except for the radiologist at Harvard, who said that tumor is totally insensitive to radiation and all you are going to do is destroy her central nervous system and you won't get any benefit out of it. That was out of about seven universities we called.

We took his advice and wound up in the hands of a very great neurosurgeon at Children's Hospital in Boston.

I have been troubled, deeply troubled, ever since then about that situation which I know still exists to a large extent. What I want to know is why is there not some kind of master key that every doctor in the United States can push for every condition, and find out what the most effective treatment for that particular problem is.

In this computer age, it seems inexcusable not to have such a system.

Dr. BRODER. Sir, I have jurisdiction over the cancer part of your master list, and, although I would not call it a master key, we do have something that approximates what you have suggested.

We have set up a computerized system—in collaboration with the National Library of Medicine—which is user friendly for doctors, and which they can use out of their personal computer in their own office or at a local medical library. It is abbreviated PDQ, for Physician Data Query. We have a special monitoring board, editorial board, which reviews protocols and state-of-the-art information.

It is a requirement, a nonnegotiable requirement, for all NCI funded studies to be entered into this computer, and for all NCI funded physicians to have their names and their level of expertise entered into this computer.

It is possible for a doctor to use the PDQ system to provide relatively quick access to state-of-the-art information, so that families do not confront the suffering that you have had to endure in another era.

I cannot tell you that PDQ has eliminated the problem. But I do believe that addressing the specific issue you have raised has been a major priority of the Cancer Institute.

Such activities are funded out of our research management and support line.

Senator BUMPERS. I'm very impressed with your answer and I'm encouraged by your answer.

I guess it is unfair to ask you if the other institutes are up to speed like you are on this. Does this situation exist in any other institute except cancer?

Dr. WYNGAARDEN. We cannot say that it exists universally, but there are other data banks. The AIDS data bank is one example. There is a data bank in neurology as well, I believe, and there may be some others.

Dr. Goldstein can speak to that later.

PDQ

Senator BUMPERS. All right. I will not pursue that now.

Dr. Broder, your answer is a satisfactory answer and I am encouraged by it.

Dr. BRODER. Perhaps I could just make one comment.

We would hope that there would be an era in which patients will view themselves as appropriately entitled and enfranchised to ask of a doctor, except under an emergency condition, what are the options that you have reviewed, and if it affects the cancer treatment, we would hope that patients would feel entitled and enfranchised to ask the doctor what does the PDQ system say about my disease, and what are the options listed in that computer system.

Senator BUMPERS. The other thing that I might make just as an observation is this.

I was a country lawyer in a town of 1,500 people at the time. I didn't know anybody. I knew our pediatrician, and that's all. He had done a residency with this neurosurgeon down at Duke, and that is the reason we wound up in Boston.

But I'll tell you that I found out one thing. First, I don't ever take just one medical opinion. Second, I found out the very best

care in this country does not cost any more than the worst care in the country.

Thank you, Mr. Chairman.

ANIMAL VIRUS RESEARCH

Senator HARKIN. Thank you, Senator Bumpers.

One last thing.

I keep getting inputs into my office, to me, and to the subcommittee, on the potential or actual value of domestic animal virus research, and some of the possibilities that it could lead to some more knowledge about how it affects cancer.

I know that you are meeting with some people on Friday from the veterinary services, the division of the Iowa State National Veterinarians.

I appreciate that.

But I am just wondering how much has been done to look at the linkage between animal research, animal virus research, that kind of thing, and what potential linkage it might have to the human system, especially as it regards cancer.

Has there been much of that in the past at all?

Dr. BRODER. I think there has been a significant interplay between animal viral research and human viral research and understanding the viral causation of certain cancers.

This has been true for several different kinds of viruses.

Within our own institute, there has been a special interest in what are called retroviruses, and the knowledge that has been gained from animal viruses has been of immeasurable value in understanding human disease, and vice versa.

So we believe that the totality of the knowledge that we are gaining may have significant veterinary and agricultural implications, which we are very pleased to see.

So we think that knowledge cannot always be contained or anticipated in terms of what direction it will take, and we feel that animal model research is exceedingly important. We would be very committed to supporting it insofar as our budget can permit it.

Senator HARKIN. I have heard some things and I don't know how much of it is true or not. But I hear of some things that are going on out there with animal research. I know that there are some, I don't want to use the word renegade but I will use it, some renegade type of research going on, and perhaps some applications that people have made some pretty fantastic claims for.

A lot of those I always look askance at. But if there is something there, I would hope the National Cancer Institute would look at it and determine whether or not it has validity to it, or not.

So I am glad to see that you are going to meet with them and see how much of a possibility this has for transference to the human sector.

Did you have any else, Dr. Broder?

Dr. BRODER. No, sir; I want to thank you for allowing me to appear before you for the first time.

Senator HARKIN. We thank you. That's right. You took over in December, is that right? Was it December, when you took over as head of the institute?

Dr. BRODER. I was sworn in on January 10.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Well, welcome. We will see a lot of you.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CANCER DEATH RATES

Question. In 1971 when President Nixon declared war on cancer an estimated 335,000 people died of the disease. In 1989 $16 billion later in National Cancer Institute spending, it is estimated that 502,000 people will die of cancer.

I am not sure all the growth in cancer deaths is just because the population has grown. For example, let me read you part of a recent article that appeared in one of our national magazines.

> "... there is a gloomy side to the numbers if you look at them closely ... a side underplayed by the Cancer Institute.
>
> "... since 1974, the five-year survival rate has increased less than one percent and is actually declining for some kinds of cancer. The overall rate at which cancer patients die has been largely unchanged since the mid-1970s.
>
> "... equally worrisome, the overall rate of cancer, even when adjusted for the increasing age of the population, has been rising at about one percent a year for 30 years." Dr. Broder these statements are based on your own data.

How do you respond to these concerns? Are we making any overall progress on the war on cancer?

Answer. Over the past few years there has been much commentary, both written and spoken, on the question of the extent of progress against cancer. Mortality statistics have been cited to argue that progress has been slow and that any reductions in mortality have been only for the low incidence cancers.

Yet, the facts as expressed through national mortality trends demonstrate significant improvements in mortality for some age groups and cancers, while for others there is an increasing cancer burden. The cancer measures, which show clearly that there has been much progress, are not the same for all persons. A recent review of cancer statistics documents the promise of continued gains, the potential for additional progress, and the challenges posed by correcting differentials in our cancer burden. For example, persons under the age of 65 have a greatly improved prognosis for many types of cancer as compared to that for persons 65 years and older. It is clear, however, that we must concentrate on those cancers which have been increasing most rapidly (e.g., lung cancer and melanoma) for which we know the cause and can prevent, and those cancers for which early detection (e.g., routine breast physical exam and low dose mammography) has been shown to lead to significant reductions in cancer mortality.

Two of the principal factors that contribute to the increasing numbers of cancer cases and cancer deaths are the growing size of the population in the United States, and the fact that more persons today are alive at older ages. It is estimated that 1,010,000 Americans will be diagnosed with cancer in 1989, and approximately 502,000 people will die of cancer during the year. These estimates

are an increase from the 1988 estimates of 985,000 cases and 494,000 deaths. The increases have been projected based on an increase in the number of older Americans who have a higher risk for developing the disease -- one-half the cases occur in persons over age 67 -- and the continuing, but slowing increase in lung cancer. While the number of cases and deaths is increasing (at about 1.5 percent per year), the incidence rate, which reflects the risk of cancer for the individual, has shown a small decrease from 1985 to 1986.

Some highlights of the progress and challenges before us are outlined below:

-- Significant improvements in age-adjusted annual cancer mortality rates (deaths per 100,000 persons; adjusted to the 1970 U.S. standard population) have occurred during the period 1973 to 1986 even in the presence of a persistent increase in the rate at which individuals develop cancer.

-- Improvement is evident in the large reductions in the annual cancer mortality rates among persons under age 65: for example, bladder cancer mortality has decreased 29 percent; ovary, 24 percent; colorectal cancer, 14 percent; oral cancer, 17 percent; children's cancers, 35 percent; and cervical cancer, 38 percent. However, other cancers have shown increases: melanoma, up 17 percent; multiple myeloma, up nine percent; and esophageal cancer, up six percent (Table 1B). Between 1973 and 1986 the mortality rate for all cancers combined for persons under 65 decreased three percent.

-- For persons ages 65 and older the overall cancer rate has increased, but here, too, many prevalent cancers have shown declines, including colorectal cancer, five percent; bladder cancer, 18 percent; and cervical cancer, 39 percent (Table 1B). Other sites have increased in mortality, including all sites combined and all sites combined excluding lung, up 12 and three percent, respectively; lung cancer among females, up 141 percent; lung cancer among males, 30 percent; melanoma, 47 percent; and brain cancer, an increase of 54 percent.

-- Cancer mortality in children has declined 35 percent in the 14 years between 1973 and 1986, which is recognized as due to treatment, particularly treatment through the Nation's network of clinical trials and Cancer Centers.

-- The lung cancer incidence rate (cases per 100,000 persons) among males has begun to decrease; lung cancer in females continues to rise but, more recently, at a much reduced rate of increase, down from 6.3 percent per year increase to 2.8 percent per year.

-- The lung cancer mortality rate among males may have reached a peak and begun a decline after a rise of 17 percent since 1973. In contrast, the rate among all females increased 94 percent since 1973 and continues to grow at over four percent per year.

-- The age-adjusted annual mortality rate from all cancers excluding lung is down 2.1 percent since 1973, and, attesting

to the magnitude of lung cancer, mortality from all cancers combined, including lung cancer is up 5.4 percent.

- Disproportionate cancer rates among blacks (Table 2):

  -- Black males have a mortality rate approximately 40 percent higher than white males; blacks have more than three times the mortality rate of whites for esophageal cancer. The mortality rate for black women is over 16 percent higher than the rate for white women. The differences between five-year relative survival among whites and blacks by sex is particularly striking: females -- 56 percent for whites against 44 percent for blacks; males -- 46 percent for whites against 33 percent for blacks.

  -- For many cancers, black rates are increasing in contrast to decreasing rates among whites. For example, colorectal cancer mortality has fallen nine percent in whites, but has increased by 11 percent in blacks between 1973 and 1986.

These figures show both the considerable disproportionate burden borne by the black community as well as the potential for reduction of that burden. The national data show that even as colorectal cancer mortality declines among whites it increases among blacks, and similarly for breast cancer, and oral cancer. For sites such as Hodgkin's disease or testicular cancer in which mortality has fallen by nearly 50 and 60 percent among whites since 1973, the corresponding decreases in blacks are only 32 and 35 percent, respectively. Some strategies to reduce this toll are clear, reduction of smoking prevalence for one. But the reasons for some of the differences remain unclear although a likely hypothesis is the reduced access to state-of-the-art cancer care for much of the black community. Efforts are underway to reduce this gap.

While concern is high over rising breast cancer incidence rates, the increases may be due more to better and earlier detection than to a real change in prevalence. Indeed, the large increase also apparent for <u>in situ</u> breast cancer cases signals that increased early detection is taking place.

Other trend information:

-- Smoking rates continue to decline, but much more slowly in females than in males. At the current relatively low rate of decline, the percentage of female smokers will exceed that of male smokers by the year 2000.

-- As of 1987, dietary recommendations have not resulted in a change in the national <u>average</u> figures for the consumption of fat and fiber. However, there is considerable change taking place in food processing and food distribution, changes that have not, as yet, been assessed.

-- Screening figures for breast and cervical cancers have improved considerably in the black community, but less so among whites. This has resulted in blacks achieving some higher screening percentages (Pap smear and breast physical exam) than among whites.

-- SEER data indicate increases in the percentage of patients offered state-of-the-art treatments in rectal, ovarian, breast, cervix and testicular cancers.

In summary, the data show a profile of progress and challenge. Mortality is decreasing for persons under age 65 for all cancer sites combined and for a large number of specific cancers. Yet, in this age group mortality is rising from some cancers and for more cancers among persons over age 65. Decreases in colorectal cancer, bladder cancer, children's cancers, and a number of other cancers all show that combinations of early detection and treatment can reduce the cancer mortality.

On the other hand, experts have watched with dismay how lung cancer has climbed among women despite all that is known about preventing the disease. Now lung cancer mortality among women has finally overtaken breast cancer as the leading cancer killer among white women. Trends clearly indicate the same will be true by the end of this year for all women. Lung cancer accounts for over 27 percent of the age-adjusted death rate and the large increases in this disease over the past 30 years are reflected in an increase in the overall cancer mortality rate which represents all cancer sites combined. Since 1950, lung cancer mortality has risen 260 percent, while the overall cancer mortality rate, including lung cancer, has risen only 9.1 percent. If lung is excluded, the cancer mortality rate has actually declined a total of 13.2 percent since 1950. Lung cancer is highly associated with smoking, and a decline in smoking led in 1986 to decreases in the rate of new cases among white males. The 1986 figure of 80.3 cases per 100,000 males is the lowest since 1977 when the rate was 79.9. In contrast, the trend in lung cancer incidence in females continues to increase.

Prevention, however, is the key to reducing the 30 percent of cancer mortality due to smoking, and the key to reducing melanoma. But preventive regimens must still be found for other cancers, particularly two cancers showing increased incidence, non-Hodgkin's lymphoma and multiple myeloma. There is considerable evidence of the feasibility of diet- and life-style-based prevention in the dramatic decline in the incidence of stomach cancer over the last 30 to 40 years in the United States and some other countries. In many countries stomach cancer is the leading cause of cancer deaths. Much work remains to be done to find the dietary keys to prevention, although general guidelines to adopt have been developed while the research is underway.

The data also pose a major challenge to us to find additional ways to fully apply our existing knowledge. For example, if breast cancer screening was applied to its fullest extent, reductions in mortality on the order of 30 or more percent could result, based on the results of large-scale randomized trials. Data from the Health Insurance Plan of New York study of breast cancer screening began to show a differential effect of screening on mortality within the first four to five years of the study, yet mortality data has yet to show this order of magnitude of change. The problem may be in the incomplete application of our current knowledge. On the other hand, the considerable decline in the incidence of cervical cancer is in largest measure known to be due to screening, so in this case the

technology has been transferred to practice fairly effectively, although there are still some groups that have disproportionately high cervical cancer mortality rates, in particular the black community.

In summary, the data serve as assessment of the past and sentinels for the future trends in cancer. Progress has been considerable for many cancers and groups, but the challenge that remains is formidable. The statistics outlined here and in the NCI's reports give direction to research and application and indications of the future promise.

TABLE 1A
Site-specific Trends: 1973-1986
Males and Females -- All Races

SITE	ESTIMATED CASES 1986	OBSERVED DEATHS 1986	INCIDENCE RATE 1986	Percent Change 1973-86 All Ages	<65	65+
Lung	149,000	125,376	55.8	29.2	20.4	38.1
Lung (F)	49,000	40,415	36.4	86.8	60.4	127.4
Lung (M)	100,000	84,961	81.9	12.0	5.7	17.0
Melanoma	23,000	5,673	9.9	74.4	68.5	92.0
MultMyeloma	10,400	7,987	3.9	3.7	- 0.7	6.3
NonHodgkins	27,200	16,169	12.6	44.9	44.2	45.6
Kidney/Renal	20,000	8,986	8.0	19.9	15.9	24.5
Esophagus	9,300	8,918	4.0	11.3	7.9	14.6
Prostate (M)	90,000	27,261	88.9	35.6	43.8	33.9
Brain/NS	13,800	10,322	6.1	22.3	11.8	55.3
Breast (F)	123,000	40,534	104.9	17.6	11.1	29.6
Pancreas	25,500	23,456	9.3	- 3.6	-13.5	2.7
Leukemia	25,600	17,491	9.3	- 8.9	- 7.2	-10.5
ALL	12,300		1.5	16.2	20.8	-17.6
Liver	13,600	5,988	2.4	16.2	12.3	19.7
Larynx	11,700	3,610	4.4	2.1	- 2.3	8.5
Colorectal	140,000	56,862	50.5	9.4	6.7	10.9
Colon	98,000	49,231	36.2	13.9	9.2	16.3
Rectum	42,000	7,631	14.3	- 0.4	2.2	- 2.1
Ovary (F)	19,000	11,728	12.7	- 7.1	-14.1	6.4
Oral/Pharynx	29,500	8,292	10.7	- 1.9	- 4.4	1.6
Corpus (F)	36,000	5,851	21.1	-27.1	-42.4	5.4
Bladder	40,500	9,654	16.8	10.3	7.7	11.8
Thyroid	10,600	992	4.5	16.7	19.4	4.9
Stomach	24,700	13,854	8.1	-20.0	-17.1	-21.5
Cervix (F)	14,000	4,557	8.8	-35.9	-35.5	-37.6
Hodgkins	6,900	1,828	2.5	-16.0	-10.4	-39.8
Testis (M)	5,100	384	4.2	31.8	33.6	- 5.7
Children (<15)	6,550	2,175	13.6	7.5		
All-Lung	781,000	343,954	309.3	9.7	4.9	14.2
All	930,000	469,330	365.1	12.3	7.0	17.3

TABLE 1B
Site-specific Trends: 1973-1986
Males and Females -- All Races

SITE	U.S. MORTALITY RATE 1986	Percent Change: 1973-86 All Ages	<65	65+	5-yr. SURVIVAL 74-76	80-82
Lung	46.9	32.1	15.6	48.5	12.2	12.9
Lung (F)	27.1	93.9	60.4	140.8	15.6w	15.7w
Lung (M)	74.0	17.0	1.3	29.6	10.9w	11.7w
Melanoma	2.1	27.2	16.6	47.0	79.0	80.8
MultMyeloma	2.9	23.8	8.7	32.0	24.3	26.3
NonHodgkins	5.9	20.3	2.9	35.4	46.9	50.2
Kidney/Renal	3.3	10.3	2.5	17.3	51.2	52.7
Esophagus	3.4	9.9	5.6	13.9	4.7	7.3
Prostate (M)	24.2	9.7	0.4	10.9	66.4	72.1
Brain/NS	4.0	7.8	-10.3	53.7	22.0	24.0
Breast (F)	27.2	2.0	- 3.7	10.2	74.0	75.4
Pancreas	8.4	- 1.7	-11.4	4.0	2.7	3.0
Leukemia	6.4	- 4.2	-13.8	4.4	33.3	33.3
ALL	0.6	-21.2	-24.0	-10.9		
Liver	2.2	- 4.6	- 6.0	- 3.7	3.8	3.7
Larynx	1.4	- 6.8	-13.2	- 0.1	65.3	66.5
Colorectal	20.1	- 7.6	-13.7	- 4.8		
Colon	17.4	0.1	- 6.6	3.2	49.8	54.8
Rectum	2.7	-38.0	-40.3	-37.0	48.0	52.0
Ovary (F)	7.7	- 8.5	-23.5	12.1	36.4	38.6
Oral/Pharynx	3.1	-13.5	-17.1	- 9.6	52.8	51.2
Corpus (F)	3.6	-19.2	-32.1	-10.4	88.1	81.9
Bladder	3.3	-20.3	-29.2	-17.8	72.1	76.9
Thyroid	0.4	-21.6	-25.5	-19.4	91.9	93.8
Stomach	5.0	-27.6	-24.7	-29.0	14.9	16.8
Cervix (F)	3.2	-38.3	-38.2	-38.6	68.2	66.0
Hodgkins	0.7	-48.7	-50.7	-44.5	70.9	75.1
Testis (M)	0.3	-59.6	-60.0	-56.7	78.4	91.2
Children (<15)	3.6	-34.8			55.0w	65.2w
						w=white
All-Lung	124.4	- 2.1	- 9.5	3.2		
All	171.3	5.4	- 3.2	12.0	48.9	49.8

TABLE 2

Differences in Cancer Incidence, Mortality and Survival
By Race 1/

Incidence, Mortality and 5-Year Relative Survival

	Males		Females	
	Whites	Blacks	Whites	Blacks
Mortality (1986)	212.7	296.4	138.2	161.1
Incidence (1986)	423.4	502.0	332.3	325.5
5-yr relative surv. (1980-85)	45.6	32.7	56.1	44.3

5-Year Relative Survival (1980-85)

Site	Blacks	Whites
All sites	38.1	51.1
Oral cavity and pharynx	30.6	53.8
Esophagus	5.8	8.1
Stomach	18.5	15.5
Colon	47.9	55.2
Rectum	38.8	52.9
Larynx	52.9	68.2
Melanoma of the skin	66.4	81.0
Breast (females)	63.5	76.3
Cervix uteri	59.3	66.9
Corpus uteri	52.0	83.4
Prostate	62.8	73.4
Urinary bladder	56.1	77.7
Brain and nervous system	29.5	23.5

Differences in Cancer Incidence, Mortality and Survival
By Race

	Incidence Rates			
	Males		Females	
Site	Whites	Blacks	Whites	Blacks
Oral and pharynx	15.9	23.7	6.1	5.9
Esophagus	5.1	20.9	1.8	5.8
Stomach	10.7	17.9	4.5	9.1
Colon	42.3	41.2	31.6	36.3
Rectum	19.1	14.6	10.8	10.5
Urinary bladder	31.5	16.2	7.8	5.0
Liver	3.0	5.6	1.1	2.4
Pancreas	10.7	15.1	7.8	13.2
Larynx	7.9	12.7	1.5	1.9
Lung and bronchus	80.3	128.1	37.0	43.0
Breast	0.7	1.3	107.3	93.3
Prostate	87.7	123.4	--	--

1/ Incidence and mortality rates are expressed per 100,000 persons and are age-adjusted to 1970.

TABLE 2 Continued

Differences in Cancer Incidence, Mortality and Survival
By Race

	Mortality Rates			
	Males		Females	
Site	Whites	Blacks	Whites	Blacks
Oral and pharynx	4.4	9.4	1.7	2.4
Esophagus	4.8	15.3	1.3	3.9
Stomach	6.7	13.3	2.9	5.6
Colon	20.8	22.5	14.7	18.2
Rectum	3.7	3.9	2.0	2.2
Urinary bladder	6.0	4.2	1.7	2.4
Liver	2.9	5.4	1.3	1.9
Pancreas	9.7	13.2	7.0	10.2
Larynx	2.3	5.0	0.4	0.9
Lung and bronchus	72.3	98.4	27.4	26.4
Breast	0.2	0.3	27.3	29.0
Prostate	22.4	46.5	--	--

1/ Incidence and mortality rates are expressed per 100,000 persons and are age-adjusted to 1970.

Question. Dr. Broder, your predecessor Vince DeVita issued a report several years ago setting the goal of a 50 percent reduction in cancer mortality by the year 2000. Is this goal achievable?

Answer. Yes, this goal is achievable, but with some caveats. It will be necessary to continue the Institute's efforts to expand accrual into clinical trials as well as maintain and expand the resources such as cancer centers. These resources, located throughout the Nation, permit the promulgation and translation of research results, thereby assisting in the achievement of the stated reduction in mortality. It is interesting to note that the state of Utah has, in my opinion, already reached the year 2000 goal. For lung cancer and colon cancer, their mortality rate is already below that needed to attain the 50 percent reduction in mortality. If we have achieved it in one state, we should be able to replicate it in other geographic regions. The challenge we face is to promulgate the latest findings in such a manner to get the results of basic research into actual clinical application and practice throughout the Nation.

CANCER CENTERS

Question. Dr. Broder, your budget shows that there is a $1.2 million reduction in your cancer center line item although you show funding for 60 centers in fiscal year 1990, the same number as were funded in fiscal year 1989. I understand that 17 centers are up for renewal. Is it accurate to say that it is expected you will lose five to seven centers based on the current funding level requested?

Answer. The cancer portion of the centers budget shows a reduction of $1.2 million between fiscal years 1989 and 1990, however, if the AIDS budget for centers is included, the centers budgets for 1989 and 1990 are level.

With an essentially level centers budget in fiscal year 1989, NCI with the advice of the National Cancer Advisory Board was faced with a difficult choice: whether to pay all centers competing for renewal at a reduction of 30 percent below recommended levels, or to phaseout five or six centers and pay the remaining centers at a smaller reduction of 15 percent, that is, 85 percent of levels recommended by peer reviewers. The latter operating policy was selected.

In fiscal year 1990, there will be 15 centers up for competitive renewal plus potential resubmissions from those centers phased out in 1989. In fiscal year 1990, the centers funding situation will be similar to that in 1989. NCI will have to phase out an additional four or five competing centers in order to fund the remaining 11 or 12 competing centers at 85 percent of recommended levels.

GENE THERAPY

Question. What progress is being made in gene therapy to treat cancer?

Answer. The term "gene therapy" refers to the use of genetic material (DNA or RNA) as a treatment for cancer. This may take the form of:

- replacing the particular gene, called the "suppressor oncogene," whose absence has led to the uncontrolled growth and malignant transformation of the cell;

- inactivating the "dominant oncogene," whose activation has transformed the cell into a cancer cell, through the use of oligonucleotides which are complementary to the DNA or RNA of the oncogene and can bind to and block the expression of those genes; and

- altering the genetic structure of tumor-fighting immune cells to make them more effective killers of cancer cells.

There has been much exciting progress made in each of these areas over the past few years. Tumor suppressor genes long known to be involved in certain childhood tumors, such as retinoblastoma and Wilm's tumor of the kidney, have recently been discovered to be involved in some common adult cancers, such as colon and lung. While the ultimate goal of this research is the identification and replacement of the genes lost in cancer cells as a treatment for cancer, more work needs to be done in the laboratory in defining the precise location and identity of these tumor suppressor genes, identifying the proteins encoded by these genes, and understanding the mechanism by which these proteins act to prevent malignant transformation of the cell before the application of this treatment to patients with cancer can begin.

When certain genes which lie dormant in normal cells become active in the wrong place at the wrong time, a cell can begin to grow and spread in an uncontrollable fashion and become a cancer

cell. Such dominant oncogenes, like n-myc or abl, have been recognized to play causative roles in the development of neuroblastoma and chronic myelogenous leukemia, respectively. Increased gene copy number and/or activity can be blocked in cell culture by the administration of short nucleotide chains, called oligonucleotides, which are complementary (and therefore bind to and inactivate) the DNA or RNA of the dominant oncogene. The technical difficulties associated with the development of oligonucleotides which can enter a cell and successfully bind to a target gene without being digested, degraded, or otherwise inactivated have been formidable. Nevertheless, significant progress has been made against these obstacles and oligonucleotides are now in the preclinical phase of testing in laboratory animals. If successfully developed, oligonucleotides represent a therapy which can be quite specific to the targeted cells and may be as useful in the treatment of AIDS as it can be in cancer.

BLACK AMERICANS AND CANCER DEATH RATES

Question. I understand that American blacks have a higher cancer death rate for many types of cancer including cancer of the lung, uterus, prostate, head and neck. Other than lifestyle differences and the availability of good medical care, are there reasons that blacks have a higher death rate for these types of cancers?

Answer. Available data indicates that for all cancer sites combined, when compared to whites, blacks have a 10 percent greater risk of developing cancer (Table 1) and a five-year survival rate which is 30 percent lower than expected (Table 3). High incidence rates coupled with low survival rates leads to a mortality rate 30 percent higher than that for whites, 40 percent higher for black males and 20 percent for black females (Table 2).

The age-adjusted cancer incidence rate for esophageal cancer among blacks is 3.7 times the expected rate relative to the white rate and ranks first (poorest) among the major cancer sites (Table 1). The incidence of cancer of the cervix uteri is over twice as frequent for blacks while the rates for stomach and prostate are slightly less than twice as frequent for blacks. Blacks are not at an increased risk for developing all cancers. Blacks have about half the risk of whites for developing cancers of the corpus uteri and urinary bladder. Black females have an incidence rate for breast cancer that is 90 percent that of whites. The risk of developing ovarian cancer among black females is 70 percent that of white females.

The five-year relative survival rates for blacks are typically significantly lower than those for whites (Table 3). The rate for the combination of all cancer sites, including both sexes, (38.1), is only 70 percent of the white rate of 51.1 percent. Among the individual cancer sites, the poorest survival rates, relative to those for whites, are seen for cancers of the oral cavity and corpus uteri with five-year survival rates 40 percent lower than that for whites, while cancers of the esophagus, and urinary bladder have survival rates 30 percent lower than those for whites. The five-year survival rates of breast cancer in females is 20 percent lower for blacks than for whites.

The age-adjusted mortality rate for all cancer sites and both sexes combined is 30 percent higher for blacks than for whites, 40 percent for males and 20 percent for females. The mortality rate is a combination of the incidence rate and the survival rate. Thus it is possible to have a lower incidence rate of a certain cancer but when this is coupled with a poor survival rate, the mortality rate will be high. Esophageal cancer ranks first (that is, has the poorest) black-white mortality ratio among the major cancer sites with a mortality rate among blacks over three times higher than the rate for whites (Table 2). The mortality rate for prostatic cancer is over twice as high among blacks while the mortality from cancer of the cervix uteri is almost three times as high among blacks as among whites. It is most notable that for cancer of the corpus uteri, the mortality rate among black females is almost twice that of whites while the incidence rate is 60 percent lower. This disparity is caused by the fact that the survival rate for this cancer is only 60 percent of that for white women. The mortality rate from cancer of the urinary bladder should be much lower for blacks than whites on the basis of incidence, but because of the poor survival rate the mortality rates are essentially the same.

Some of the factors thought to contribute to these excessive cancer burden patterns among blacks of generally high incidence, low survival and higher mortality are high tobacco usage rates including cigarettes and smokeless tobaccos; excessive use of alcohol; over exposure to occupational risks and a less nutritious diet; and less access to state-of-the-art cancer control services for early detection, diagnosis, and treatment. These risk factors are highly correlated with Socio-Economic Status (SES). Persons in low SES strata smoke more, and, are targeted for advertising by tobacco companies, drink more, and have the higher risk occupations.

Increasing numbers of studies are also indicating strong relationships between low SES and poor survivorship from cancer. This may have to do with poor access to or the lack of availability of quality medical care to persons living in the inner cities. These persons are typically underinsured and thus unable to take advantage of medical care for screening and routine checkups. Blacks, typically, are diagnosed with more advanced stage cancer and have longer delays between diagnosis and treatment than whites. Both these factors contribute to a poorer survivorship.

Additionally, factors related to host vulnerability and immune function, co-morbid conditions, tumor cell types, and nutritional status may also help explain the excessive cancer burden of blacks. These areas need additional research to more fully determine their impact on cancer among blacks.

TABLE 1

Age-adjusted cancer incidence rates per 100,000 population
SEER, 1985-1986

Cancer site	Incidence rate per 100,000 Blacks	Incidence rate per 100,000 Whites	Ratio Blacks/Whites
All sites	398.6	366.5	1.1
males	507.1	422.9	1.2
females	323.1	334.9	1.0
Esophagus	11.9	3.2	3.7
Oral cavity	28.7	10.8	2.6
Cervix	15.6	7.6	2.1
Stomach	12.7	7.1	1.8
Prostate	125.6	86.4	1.5
Lung & bronchus			
males	127.9	81.0	1.6
females	41.7	36.3	1.2
Colon	38.9	36.8	1.1
Breast (females)	92.7	106.2	0.9
Rectum	11.7	14.8	0.8
Ovary	9.5	14.1	0.7
Corpus	14.3	22.7	0.6
Bladder	10.0	17.7	0.6

TABLE 2

Age-adjusted cancer mortality rates per 100,000 population
United States, 1985-1986 1/

Cancer site	Incidence rate per 100,000 Blacks	Incidence rate per 100,000 Whites	Ratio Blacks/Whites
All sites	216.0	167.8	1.3
males	297.2	212.6	1.4
females	160.1	138.2	1.2
Esophagus	8.7	2.8	3.1
Cervix	7.4	2.7	2.7
Prostate	46.5	21.9	2.1
Stomach	8.8	4.6	1.9
Oral cavity	5.4	2.9	1.9
Corpus	5.9	3.5	1.7
Lung & bronchus			
males	98.2	72.3	1.4
females	25.9	27.1	1.0
Colon	20.3	17.4	1.2
Breast (females)	28.8	27.4	1.1
Rectum	2.8	2.8	1.0
Bladder	3.2	3.4	0.9
Ovary	6.2	7.9	0.8

1/ The mortality data used in this table are for the entire United States.

TABLE 3

Five-year cancer relative survival rates
SEER, 1980-1985

Cancer site	Five-Year Relative Survival Blacks	Whites	Ratio Blacks/Whites
All sites	38.1%	51.1%	0.7
males	32.7	45.6	0.7
females	44.3	56.1	0.8
Corpus	52.0	83.4	0.6
Oral cavity	30.6	53.8	0.6
Esophagus	5.8	8.1	0.7
Bladder	56.1	77.7	0.7
Rectum	38.8	52.9	0.7
Breast (females)	63.5	76.3	0.8
Colon	47.9	55.2	0.9
Lung & bronchus			
males	10.4	11.9	0.9
females	14.7	15.7	0.9
Prostate	62.8	73.4	0.9
Cervix	59.3	66.9	0.9
Ovary	38.3	38.4	1.0
Stomach	18.5	15.5	1.2

STATE-OF-THE-ART TREATMENTS

Question. I understand, from a GAO report, that only one-third of the doctors across the country are using state-of-the-art cancer treatments. How much is requested in fiscal year 1990 for disseminating information about state-of-the-art treatments and how does this compare to the fiscal year 1989 level? I understand that these funds are included in two separate line items, research management and support and cancer prevention and control.

Answer. In support of our information dissemination programs in 1989, NCI will obligate an estimated $91.6 million, and as provided by the 1990 request level, about $92.5 million. The preponderance of these funds are included within research management and support and cancer prevention and control.

NEW DRUGS AND TREATMENTS

Question. I understand that every year approximately three new drugs are put in Phase I testing by the Cancer Institute. What has happened in the last year with regard to new drugs for the treatment of cancer?

Answer. For the fiscal year 1988, an Investigational New Drug (IND) Application allowing clinical trials in patients to begin, was submitted to the Center for Drug Evaluation and Research, Food and Drug Administration (FDA), for each of the following compounds: Dideoxyadenosine, Buthionine Sulfoximine, Hepsulfam, Chloroquinoxaline Sulphonamide, Fostriecin, Ipomeanol, Pyrazine Diazohydroxide, and Dideoxyinosine.

INDs were submitted to the Center for Biologics Evaluation and Research, FDA, for the following agents: IL-2 + Tumor Infiltrating Lymphocytes, Interleukin-1 Alpha, Interleukin-1 Beta, Interleukin-4, Macrophage Colony Stimulating Factor (M-CSF), Monoclonal Antibody OKT-3, Monoclonal Antibody 14.18, Monoclonal Antibody 14G2A, Monoclonal Antibody 11C64, Monoclonal Antibody Lym-1, Monoclonal Antibody 1F5, Monoclonal Antibody B1, Monoclonal Antibody NRCO-4, Monoclonal Antibody 96.5, Second Generation B72.3, Monoclonal Antibodies, Chimeric Monoclonal Antibody B72.3, Expanded LAK Cells, and Educated Lymphocytes.

During 1988, 24 new drugs or biologicals entered Phase I dose seeking trials in man under NCI sponsorship while 97 were under evaluation in Phase II, or disease-oriented testing. Among these agents, several showed interesting antitumor activity.

Taxol, an inhibitor of cell division, or mitosis, originally isolated from the bark of the taxus species of trees, has produced responses in malignant melanoma, a highly refractory skin tumor, and in 40 percent of patients with ovarian cancer. Plans are underway to combine taxol with cis-platin in a pilot study. Although this is a promising agent, its evaluation has been slowed by the severe shortage of this natural product.

2-fluoro-ara-AMP, a purine analog and an inhibitor of DNA synthesis, produced a high response rate, including 15 percent complete responses, in patients with chronic lymphocytic leukemia. This is the first antimetabolite to demonstrate activity in this disease.

A new folic acid analog, related to the commonly used agent methotrexate, but possessing unique features that circumvent drug resistance, has entered clinical trials. Trimetrexate, a lipid soluble agent that bypasses the need for an active transport system into cells, has activity against colon cancer, and parenthetically, against parasitic organisms that commonly infect AIDS patients, such as pneumocystis carinii pneumonia. A second antifol 10-ethyl, deaza-aminopterin (10-EDAM), currently under development by CIBA-Geigy, produced responses in six of 19 lung cancer patients in its initial clinical trial.

Two new drugs, SR-2508 and Ro-03-8799, which sensitize poorly oxygenated tumor cells to irradiation, entered initial trials in 1987 and 1988, and demonstrated less toxicity to the nervous system than prior standard sensitizers of the nitroimidazole class.

Colony stimulating factors, which stimulate the proliferation of normal bone marrow elements, entered clinical evaluation in 1987 and 1988 and provided protection against chemotherapy-induced depression of the white blood cell count, and accelerated the recovery of transplanted bone marrow.

Initial clinical experiments with IL-2, cyclophosphamide, and tumor infiltrating lymphocytes (TIL cells), have produced responses in nine of 15 patients with malignant melanoma. These cells, harvested from tumor fragments and expanded in tissue culture, were shown to localize selectively in sites of tumor deposit, and to have

much greater antitumor activity than the non-specific LAK (lymphokine activated killer) cells, although the latter cells are consistently effective in producing complete responses in 10 percent of patients with renal cell cancer.

The combined use of IL-2 and interferon-alpha, a highly potent combination in experimental systems, has produced initial responses in patients with renal cell cancer. Interferon increases the expression of surface proteins on tumor cells, making them more susceptible to recognition and killing by IL-2 stimulated lymphocytes.

Question. I understand that last year a number of new cancer treatments have proven effective. For example, clinical trials have shown that each year about 5,000 women with breast cancer that has not spread from underarm lymph nodes can benefit from either chemotherapy or hormonal-therapy after surgery. Could you tell us a little more about the several new cancer treatments that have proven effective over the last year and what progress is being made to encourage the medical community to use these new treatments?

Answer. The Institute is continually striving to encourage the use by the medical community of the latest treatment regimens uncovered through clinical trials.

- NCI Progress in the Dissemination of New Treatments

While it is estimated that only one-third of doctors across the country are using state-of-the-art cancer treatment, NCI continues to support a dynamic multi-faceted information dissemination program to not only directly address the practicing physician community, but also to provide cancer research data to cancer researchers and up-to-date treatment and prevention guidance to the general public.

In direct response to the need to provide physicians and health care workers access to information regarding state-of-the-art cancer treatments, the Institute established several years ago the Physician Data Query (PDQ) system. It is estimated that widespread use of this on-line data system alone could reduce cancer mortality by an estimated 10 percent by effectively applying known cancer treatments. A planned expansion of PDQ (PDQ-P) is now underway to provide easy access to information on cancer prevention, including tobacco use, nutrition, and carcinogen exposure.

As a direct service to the public, in 1976 the NCI established the Cancer Information Service (dial 1-800-4-CANCER). This service provides timely and accurate information to the public and is manned by trained personnel in regional offices; the annual volume of calls now exceeds 400,000. In addition, NCI media activities include annual media campaigns that tie in to cancer education programs. Press kits, public service announcements (e.g., promotion of 1-800-4-CANCER), and other media projects are developed to focus on cancer prevention and patient information.

Regarding scientific information communication, the NCI provides support for the development and maintenance of databases at the international level. Such programs facilitate the rapid and efficient transfer of technical data, enabling the entire cancer

research community to stay on the cutting edge of research. In keeping with this same purpose, the NCI also directly supports the communication of technical information to the research community.

The Community Clinical Oncology Program (CCOP) consists of 52 community programs including 240 hospitals across the country involving practicing physicians in clinical trial research in cancer treatment, as well as in programs on cancer prevention and control. Approximately 1,800 physicians participate.

The Clinical Cooperative Group Program consists of 11 multi-institutional consortia of clinical investigators conducting comparative trials of cancer treatment. Approximately 3,500 physicians enter 25,000 patients on cooperative group clinical trials annually and follow about four times that many who entered studies in previous years. These physicians also care for or consult on the care of approximately 200,000 of the 450,000 new cancer patients diagnosed annually.

An arm of this program, the Cooperative Group Outreach Program (CGOP), allows individual community oncologists to enter their patients in state-of-the-art clinical treatment trials under the guidance of Clinical Cooperative Group institutions. Five of the 11 cooperative groups conduct such outreach efforts, involving approximately 3,000 community physicians.

NCI programs are directly aimed at increasing the use of state-of-the-art treatments by practicing oncologists and reach at least 8,300 doctors annually. If one uses the 12,000 physicians in the United States who treat cancer patients for the majority of their practice and are listed in the PDQ Directory file as an estimated denominator, approximately 70 percent of oncology physicians are reached by NCI programs aimed at dissemination of treatment information.

- Cancer Treatment:

In the past year several new cancer treatments in breast, prostate, colorectal, lung and pediatric cancers have proven effective.

-- Breast Cancer

In the past year, three NCI-funded randomized clinical trials in node negative breast cancer were analyzed with each showing an advantage as measured by disease-free survival for the treated patients compared to those receiving no adjuvant therapy. The results of these three studies were made public through the use of a Clinical Alert. In the National Surgical Adjuvant Breast and Bowel Project (NSABP) study, node-negative patients with estrogen receptor negative tumors were treated with methotrexate and 5-fluorouracil or no additional treatment following surgery. At four years, treated patients had an 80 percent chance of being disease-free while untreated patients had only a 72 percent chance of being free of recurrence, a difference that was highly statistically significant. This therapeutic benefit was observed for patients under and over the age of 50. No difference in survival has yet been observed.

In another study, estrogen receptor positive, node-negative patients were randomized to tamoxifen or to a placebo. There was a statistically significant difference in disease-free survival favoring the tamoxifen treated patients. Overall survival differences have not been identified at this time.

In a Cooperative Group Intergroup study, patients with node negative breast cancer were randomized to either Cytoxan Methotrexate 5-FU Prednisone (CMFP) or observation. Eligibility included all estrogen receptor (ER) negative tumors as well as estrogen receptor positive tumors greater than three centimeters. A disease-free survival advantage was identified for the treatment arm of this study which when analyzed by subsets was present for premenopausal and postmenopausal patients as well as for ER positive and ER negative patients. No survival advantage is detectable yet between the two groups.

-- Urologic Cancer

During the past year, the prostate intergroup study has matured and has identified a modest but statistically significant survival advantage for combined leuprolide + flutamide compared to leuprolide alone. Further follow-up will better define the extent of this survival advantage.

A study to test the benefit of preoperative chemotherapy using the MVAC regimen in locally advanced bladder cancer has been started during the past year. The study is designed to give three courses of MVAC followed by radical cystectomy versus radical cystectomy alone.

The population of patients with poor risk germ cell tumors has been further defined by investigators at Memorial Sloan-Kettering Cancer Center. Additionally, the less toxic combination of cis-platin and VP-16 has produced equivalent results to VAB-6 in an early analysis by the same investigators.

An intergroup study of patients with advanced Stage II testicular seminoma has recently been started and will take three to five years to complete. This study follows important leads suggesting that chemotherapy reduces distant recurrence compared to the standard of treatment for early stage testicular cancer, radiotherapy.

-- Colorectal Cancer

Results have been published of a trial of adjuvant therapy in colon cancer which accrued approximately 1,200 patients between 1977-1984. It compared 5-FU/MeCCNU/VCR chemotherapy, BCG, and observation for patients with Dukes'B and C lesions. Average follow-up is 59 months. The data show improved disease-free and overall survival for chemotherapy compared with no postoperative therapy.

Another trial compared surgery plus combination

chemotherapy or radiotherapy with surgery alone in patients with locally advanced rectal cancers. More than 500 patients have been entered to date, with results suggesting statistically significant benefit in survival for treatments with chemotherapy.

New adjuvant trials were activated in 1987 both in colon and rectal cancer. Both trials will employ the previous best chemotherapy arm of MOF (MeCCNU, Vincristine, 5-FU) randomized against chemotherapy with 5-FU/leucovorin. In addition a further comparison in the rectal adjuvant trial of chemotherapy alone versus chemotherapy plus irradiation will be done. Both the colon and rectal trials will also incorporate tumor sampling for in vitro determination of thymidylate synthetase activity and total folate pools to determine if some prediction of responsiveness can be made.

Results have been reported of a trial of adjuvant treatment of rectal carcinoma in 200 stage B_2 and C patients in which patients were randomized to radiation alone or radiation preceded and followed by chemotherapy. Median follow-up is 29 months. Preliminary analysis, confirmed now by longer follow-up, suggests a significant advantage in time to recurrence in the combined modality arm.

Results have been reported in a trial of adjuvant treatment for colon cancer in 308 stage B_2 and C patients in which they were randomized to levamisole with or without 5-FU versus observation. Both experimental arms show preliminary, significantly improved time to progression and survival compared to the surgery alone arm. Based on this experience, a confirmatory intergroup Phase III trial in adjuvant treatment of colon cancer was started in 1985 and recently completed.

-- Lung Cancer

At last year's American Society of Clinical Oncology (ASCO) meeting, the Cancer and Leukemia Group B (CALGB) reported early closure of a positive trial showing the benefit of induction cis-platin and vinblastine before radiation for locally advanced non-small cell lung cancer.

The Lung Cancer Study Group, in a series of trials examining the role of CAP chemotherapy, have shown that such treatment is superior to BCG/levamisole in delaying recurrence and prolonging survival for patients with locally advanced tumors of non-squamous histology, who can first be rendered free of gross disease by surgery. These patients are at high risk of early relapse without such adjuvant therapy.

There are plans to investigate a number of promising new approaches to early diagnosis, accurate staging and treatment of early stage disease. These include the use of indium-labeled monoclonal antibodies and their correlation with pathological findings at the time of surgery; hematoporphyrin derivatives with argon lasers for the diagnosis and treatment of carcinoma-in-situ; evaluation of the use of IL-2 to alter the activity of tumor infiltrating lymphocytes; and clinical-

pathological correlative studies of newer techniques of imaging the thoracic contents. In addition, a tumor repository has been established to determine whether oncogene and growth factor expression in patients is correlated with their clinical outcome.

-- Pediatrics

An Intergroup Rhabdomyosarcoma Study enrolled 1,002 eligible patients and asked four questions based on extent of disease at diagnosis. Combining all patients, disease-free survival (65 percent) and survival (62 percent) in this study improved significantly over that obtained in the previous study. The major improvement was in Group III (patients with bulky residual disease but no metastases: five-year survival 64 percent versus 52 percent), attributable to intensification of therapy and patients with cranial parameningeal primary sites (five-year survival 65 percent versus 45 percent) associated with the introduction of CNS prophylaxis.

Investigators in the Pediatric Oncology Group reported promising results of therapy for patients with so-called "lower risk" acute lymphoblastic leukemia, who unfortunately still suffer a 20 to 40 percent relapse rate on current therapies. Utilizing early intensive 6-mercaptopurine and methotrexate in an effort to rapidly reduce leukemic cell numbers and thereby minimize mutation to a drug resistant state, and to eradicate leukemia cells, these investigators have observed three relapses among 62 previously untreated patients, with a median follow-up of 28 months. Fifty-nine patients, of whom 26 are off therapy, are in complete remission, for an actuarial disease-free survival of 94 percent at three years.

The Children's Cancer Study group has demonstrated that intrathecal methotrexate provides adequate central nervous system therapy in acute lymphoblastic leukemia in patients with intermediate risk features and an age of less than 10 years. Also, in association with similar findings in patients with low risk features, it permits the elimination of cranial irradiation, and the attendant risks of decrement in IQ and academic achievement, in over half of all patients without eliminating treatment success.

A collaborative randomized trial evaluating the benefit of ifosphamide and etoposide when added to the standard therapy of newly diagnosed Ewing's sarcoma has been started. Preliminary evidence indicates that the former agents are extremely active in this disease, at least in the setting of recurrent disease. The establishment of benefit, or lack thereof, of these agents when combined with vincristine, adriamycin, dactinomycin and cyclophosphamide, is the leading question, regarding the optimum treatment of this disease.

PROGRESS IN THE TREATMENT OF CANCER

Question. Dr. Broder, I understand that from the point of a researcher having a new idea about a treatment or drug to the time that it is available for use takes approximately 10 years. And

before it is generally used widely by practicing physicians takes almost 15 years. Are you satisfied with this pace of implementing new and exciting ideas about the treatment of cancer into general practice?

Answer. It takes at least that long. Clinical trials are needed to test therapies and they take time. Trials have to be designed, patients have to be enrolled, and about five years is needed to show an improvement over standard therapy. Then it requires additional time to evaluate and disseminate results in scholarly journals.

NCI is trying to expedite this process. For instance, a major campaign is taking place to speed accrual of patients onto trials. If the number of patients needed to answer the study questions can be enrolled quickly, instead of over a period of years, the trial is shortened.

In addition, NCI is meeting monthly with the Food and Drug Administration to evolve new end points for testing that allow for quicker evaluation of results and to improve ways to make "experimental" treatments available to those for whom it is the only treatment, while allowing continued evaluation.

Communication to the public and to health professionals is a key factor in speeding adoption of new therapies. NCI has an easy access database system of information called PDQ (Physician Data Query) on state-of-the-art treatments and clinical trial opportunities. Furthermore a toll-free number, 1-800-4-CANCER, connects with a nationwide information data bank, the Cancer Information Service (CIS), which is available to patients and families as well as physicians. Counselors will answer this number and give information on cancer and treatments. PDQ can be reached through this number as well.

NCI is exploring ways to speed information about new therapies to physicians and last year sent out a "clinical alert" after results of clinical trials demonstrated benefit from the use of adjuvant therapy for women with breast cancer. This alert got information to physicians nine months before they were published in a scientific journal. Other variations of communications to doctors are being explored.

IOM CANCER CENTER STUDY

Question. Dr. Broder, last year we requested a report from the Institute of Medicine regarding the cancer centers in your Institute.

The report recommends that you "take immediate steps to avert a crisis in the funding of the program during the current fiscal year 1989. The Committee recommends further that the directors of NCI and the National Institutes of Health, with the Secretary of the Department of Health and Human Services, work with the appropriate committees of Congress to develop an adequate budget for the Program's next fiscal year (1990)."

Now, I understand that because of insufficient funds, we are

likely to lose a number of cancer centers in fiscal year 1989, which I suppose is the crisis the report talks about. How many centers, of the 59 NCI now funds, would lose funding this year, and how many additional centers would lose funding in fiscal year 1990, if the President's budget were adopted?

Answer. To accomplish the funding levels contained in the President's Budget, four or five centers will be phased out in fiscal year 1989, with a similar number proposed for phase out in fiscal year 1990.

Question. Also, have the meetings been held with the Director of the NIH and the Secretary of Health and Human Services to avert "the crisis" for fiscal year 1989, as the report recommends and, if not, when will they be held? What plans are you making to search for funds within this Institute to avert "the crisis" the report speaks of?

Answer. We have not held specific meetings with the NIH Director and the Secretary, DHHS on this issue. I do not foresee the need to initiate such meetings. The Institute has received funds appropriated by the Congress for the total cancer program and within those funds we are constantly, with the advice of our outside advisory bodies, monitoring and altering program levels. Through this process we balance the many competing demands and opportunities against available resources. The requirements for additional funds into the centers program will be continually reviewed.

Question. Let me ask how much would be required, additional, in the fiscal year 1990 budget to prevent the loss of these centers and, additionally, to fund those competing centers at peer-reviewed levels?

Answer. If the fiscal year 1989 funding levels remain as currently reflected, then to fund the 60 research centers in fiscal year 1990 at their peer reviewed recommended levels would require an additional $21 million of which $7 million would fully fund the five centers being proposed for phase-out in fiscal year 1989. The balance of approximately $14 million would restore the competing centers to their peer-reviewed recommended levels, providing support for a total of 60 centers.

Question. The report indicates a number of administrative changes should take place "to increase representation of the cancer centers program in NCI planning and decision-making processes". How do you plan to accomplish this? And how do you plan to strengthen "the management capabilities of the centers program unit" as is suggested?

Answer. The National Cancer Advisory Board (NCAB) reviewed the Institute of Medicine (IOM) report on cancer centers and urged "...that the solution come, not from reordering priorities in scientific funding, but in achieving a higher priority for cancer research as well as for all of biomedical sciences as one of the Nation's priorities." The NCAB proposed that comprehensive cancer centers be clearly defined to include seven essential characteristics: basic laboratory research, basic/clinical research linkages, clinical research, high-priority clinical trial research,

cancer prevention and control research, education/training and providing updates on current technology, and information services. As recommended by the IOM, the National Cancer Institute has begun to develop a systematic program plan to consider fiscal, managerial and organizational needs of the centers program. Cancer centers' directors have elected six representatives to meet with NCI officials periodically to review cancer centers issues.

PATIENT COST IN CLINICAL TRIALS

Question. Dr. Broder, we also requested last year a report from the NCI concerning clinical research, specifically in regard to payment for patient care for those participating in clinical research. We understand from that report that there is a real problem that exists, and that claims that "are denied are not simply the additional costs of care over and above that of standard therapy, but may include the entire costs of the hospitalization".

The report also indicates that the NCI's point of view is that "patients on clinical trials receive therapy that is quite likely to be at least equivalent to or possibly better than standard treatment".

Please tell us about this situation. Is HCFA denying such payment? Are the third party carriers denying such treatment? What is being done to solve this problem, and is there anything this Committee should be doing about this?

Answer. The HCFA's Notice of Proposed Rule Making published in the January 30, 1989 Federal Register states that Medicare coverage is not provided for patients receiving treatment with experimental therapies. Experimental therapies are defined as those not approved by the FDA and those not currently used in accepted medical practice. This means, therefore, that patients receiving investigational cancer therapies on clinical trials will not be reimbursed for the costs of therapy. These denials include the non-research patient care costs incurred in the routine care of patients (x-rays, blood tests, nursing care and hospital room and board and in some cases physicians' services). Patients hospitalized for treatment with an investigational cancer therapy do not receive reimbursement for the care they would have received if treated instead with FDA-approved agents. A majority of other third party carriers including Blue Cross also have clearly-stated policies that prohibit coverage for investigational therapies.

Data do not exist describing the extent to which reimbursement is being denied by the HCFA and other insurers for investigational cancer therapies. NCI has received many anecdotal reports from patients and physicians around the country of patients being denied reimbursement by the HCFA and Blue Cross for participation in NCI clinical trials. The majority of such denials are for clinical trials that require the patient to be hospitalized to receive treatment. However, in some circumstances, reimbursement is also being denied for outpatient treatment with an investigational agent.

NCI is cooperating with the American Society for Clinical Oncology (ASCO) and with the National Coalition for Cancer Research (NCCR) in efforts to obtain information from oncologists nationally

about the extent of reimbursement denials for investigational cancer therapies. The Association of Community Cancer Centers is also in the process of collecting data about the variation in reimbursement practices nationally. These data, when available, will give some perspective on the extent to which the HCFA and other carriers are denying coverage.

However, even without the advantage of a formal database, it is clear that the HCFA and Blue Cross regulations exclude reimbursement for investigational therapies and that cancer patients are being denied coverage for participation in NCI clinical trials. This practice denies cancer patients access to innovative therapies that for many represent their only hope for meaningful therapeutic benefit. NCI's position is simply stated: investigational therapy in the context of a nationally-approved, scientifically meritorious clinical trial represents best therapy for cancer patients. We consider treatment on a clinical trial to be standard therapy for all cancers that are not reliably cured with conventional therapy. Since several cancers are not reliably cured with conventional therapy, investigational therapy represents optimal care for many cancer patients.

This policy of not providing reimbursement for investigational therapies denies patients who cannot afford to pay out-of-pocket access to the best available therapies and slows the pace of clinical research. This clinical research is needed to develop innovative, new therapies which will cure more cancer patients, thereby lowering the overall costs of cancer care.

NCI suggests that this committee consider recommending to the HCFA and other third party carriers that reimbursement be provided for the non-research patient care costs of NCI and other nationally approved, scientifically and ethically meritorious investigational cancer therapies. This committee could request that a study be done to estimate the costs to the HCFA of adopting this new policy. NCI believes that the overall costs to the HCFA of covering meritorious investigational cancer therapy would not be substantially different from the costs of caring for patients treated with approved therapies during the course of their illness. The National Center for Health Services Research (NCHSR) and NCI are collaborating on a study examining the differences in costs between hospitalized cancer patients who have been treated with FDA-approved therapies as opposed to those treated with investigational therapies. We anticipate that preliminary results from this study will be available in the fall of 1989.

SURVIVABILITY BENEFITS FOR BREAST CANCER NEED FURTHER STUDY

Question. According to a recent GAO study, the percent of patients receiving chemotherapy following surgery for premenopausal women with breast cancer has increased from 23 percent in 1975 to 69 percent in 1983. However, when the data on patients who received this treatment are subjected to statistical tests, they show no statistically significant improvement in patients' survival. GAO recommended and the Department of Health and Human Services agreed that a study to determine why there has been no visible improvement in the survival of premenopausal, node-positive breast cancer patients should be undertaken.

Has the Institute initiated plans to undertake the study of survival rates since the advent of adjuvant chemotherapy for breast cancer patients? What is the status of these plans (intramural, extramural, costs, duration of study)?

Answer. The NCI's Surveillance, Epidemiology, and End Results (SEER) Program collects incidence, survival, and mortality data on all cancers including breast cancer. The Program collects information from a large sample of the United States and its territories; 11 geographic areas in all comprising more than 10 percent of the country's population base. The annual cost of the program is in excess of $10 million, and it is not possible to identify the cost associated with the collection of only breast cancer data. The data collected include demographics, cancer site, type, stage, first course of treatment, and annual patient status.

Using these data it is possible to examine trends in cancer patient survival for specific cancer sites, including breast, and in fact, this is the study undertaken by the GAO. Unfortunately, the number of patients in the SEER data base since the advent of chemotherapy is too few to provide the statistical power to see the results expected based on the outcome of cancer chemotherapy clinical trials. In any case, analyses of this type must be interpreted with caution as factors other than treatment may influence the trends in patient survival.

NCI is very concerned, however as to the extent to which patients are, in fact, receiving state-of-the-art care. To this end a study has been launched to assess, in more detail, data from breast cancer patients as part of a special study based on the SEER data base. The study will determine whether breast cancer patients are getting appropriate chemotherapy depending on their stage of disease at diagnosis and age. Other cancer sites also are being studied including colon and bladder. The cost of this study, nearing the end of its first year is $230,000 per year and the study is expected to continue for two more years.

Another project directed toward improving our understanding of the reasons behind disproportionate survival figures between black and white cancer patients is entering the analysis phase. Data have been collected on factors related to medical care requested, types of diagnostic procedures used, and treatment received, and reactions from individuals who receive knowledge that they have or may have a diagnosis of cancer. All these factors affect health behavior and outcomes. This study includes patients with breast cancer, colon cancer, bladder cancer and cervical cancer. The special focus of the study is on the complex interplay of factors affecting patient care and their relationship to survival.

Representatives from the Division of Cancer Treatment, the Division of Cancer Prevention and Control, and the Office of the Director, NCI will meet to discuss the ways in which patterns of care and dissemination of treatment information may be most effectively studied. The recommendations of the GAO report, Cancer Patient Survival: What Progress Has Been Made?, Cancer Treatment 1975-1985: The Use of Breakthrough Treatments for Seven Types of Cancer, and Breast Cancer: Patients' Survival will be reviewed and

serve as a focus for this meeting. Selected issues to be discussed include:

- How detailed should the treatment data be?

- How useful are the surveys currently being conducted by the American College of Surgeons with regard to patterns of care information?

- Should NCI do a series of special studies using the Surveillance, Epidemiology, and End Results (SEER) program as a baseline?

- How should special populations, such as minorities and the socioeconomically deprived, be studied?

In addition to this effort, the NCI has entered into a collaborative arrangement with the Cancer Commission of the American College of Surgeons (ACoS) to study patterns of care practices in women with node-negative, early stage breast cancer. Since more than 70 percent of these women are treated initially by an ACoS-affiliated surgeon, this may prove to be a valuable source of information regarding the implementation of treatment recommendations at the community level.

Question. In general, for other types of cancer, how well documented are survival rate statistics for other relatively new treatment regimens? Please discuss several examples.

Answer. The NCI uses a nationwide network of clinical trials to assess the survival rates associated with new treatments. In turn, the survival rates for specific cancers are tracked through the Surveillance, Epidemiology and End Results (SEER) Program. The SEER program is particularly useful in comparing survival rates between different population groups thereby identifying potential targets for cancer control.

In general, the results of the clinical trials are documented through the peer-reviewed literature and the results disseminated through journals, meetings and through the NCI's PDQ information system. PDQ enables physicians to refer to state-of-the-art cancer information through a computer-based information system, and access as well, information on the clinical trials underway across the country.

The SEER Program can provide information which can be used to examine the impact of a treatment advance. For example, changes in patient survival as well as relevant cancer mortality can be examined relative to the introduction of effective new treatment regimens. An example of how the SEER data will reflect the impact of a new treatment can be seen in the data for cancer of the testis. The five-year relative survival rate for all patients diagnosed during the mid-1970s was in the mid- to high-70s prior to the introduction of chemotherapeutic advances for metastatic disease in the late 1970s. For patients diagnosed in 1981, the most recent year for which five-year survival can be calculated, the five-year relative survival rate was 94 percent. There was also a concomitant decrease in mortality for cancer of the testis.

Another example of this tracking of the impact of treatment advances can be seen in compiled data of cancers affecting children. Five-year relative survival has increased from 28 percent in 1960 to 45 percent in 1970 to 65 percent for patients diagnosed between 1980 and 1985. Concomitantly, the annual mortality rate has decreased by 35 percent in the 13-year period between 1973 and 1986, and by 38 percent in the 23-year period between 1950 and 1973. Overall since 1950, the mortality from children's cancers has decreased over 60 percent.

FUNDING OF CANCER RESEARCH

Question. Many cancer specialists are concerned that recent shifts in funding and manpower from cancer to AIDS are seriously undermining the Nation's effort to conquer cancer. For example, this year only 25 percent of new cancer research proposals approved by review committees will receive funding, compared with 60 percent in the mid-1970s. Five of the country's 60 cancer research and treatment centers are expected to lose their Federal grants in 1989, the remainder face 15 percent budget cuts. AIDS research has grown from 0.3 percent of NCI's budget in 1982 to almost eight percent in the current fiscal year. Approximately 11 percent of NCI's staff are working on AIDS rather than cancer research. NCI is currently under a partial hiring freeze imposed by the Office of Management and Budget. The departure of many senior officials during the past year has left NCI with many critical vacancies.

Has the increasing percentage of NCI's budget devoted to AIDS research seriously affected the Institute's ability to fund promising new cancer research?

Answer. NCI currently is not under a partial hiring freeze imposed by OMB. By making certain adjustments, NCI is able to fund its highest priorities in cancer research. We do believe that research successes gained in the conduct of AIDS research directly increases our knowledge base in cancer research; and vice versa.

Question. Has the emphasis on AIDS research at NCI affected the Institute's ability to recruit scientists and physicians to fill vacancies within NCI?

Answer. I do not believe that the emphasis on AIDS research has had a direct affect on our ability to recruit scientists and physicians. The scientific opportunities at the NIH and the NCI, in particular, for researchers is most unique. However, it is true that the salary competition is one of the forces making it more difficult to recruit and retain established investigators. A more noteworthy cause in our inability to recruit against scientific vacancies including scientific technical support staff, is the reduction in our FTE ceiling. While we have been successful in increasing our staffing for AIDS activities, there has been a marked decrease on the cancer side.

Question. Have the lower salary levels at NIH made it more difficult to attract scientists and physicians to fill position vacancies at NCI?

Answer. The pay discrepancy between the Federal and private sectors for white collar employees has become a nationwide problem. The National Cancer Institute is not exempt from this dilemma and continues to experience increasing difficulty in the recruitment and retention of senior scientific staff.

Staffing statistics collected by NCI for the Office of Personnel Management's (OPM) fiscal year 1989 Special Pay Rate Survey revealed that 30 percent of NCI's allocated senior scientific positions remain unfilled. The majority of these positions are Branch/Laboratory Chiefs with central and key responsibilities in the management and execution of biomedical science. As such, it is important that these positions be filled by nationally recognized scientific leaders.

For many of these positions, recruitment activity has been ongoing for months and even years. Without question, the superior salary and compensation packages available in the private sector have been a major contributing factor in NCI's inability to recruit outstanding scientists to conduct and administer major NCI research programs.

This reality is well illustrated in recent testimony presented by Dr. Anthony S. Fauci for Dr. James B. Wyngaarden, Director, National Institutes of Health (NIH) before the Commission on Executive, Legislative, and Judicial Salaries "Quadrennial Commission" which indicated that the salary and benefits available in academic institutions are much higher than the Federal government can provide. The average compensation (including base salary and recruitment and retention allowances) that NIH pays to Senior Executive Service physicians is $89,000. This is half of the $179,000 average supplemented compensation that is paid to the Chairmen of clinical science departments of American medical schools. The average salary that NIH pays other Senior Executive doctoral scientists is $73,000 or 17 percent less than the average salary for their counterparts in the basic science departments of medical schools. In addition, academic scientists have benefits which NIH cannot match, such as noncontributory and/or fully portable retirement systems, noncontributory hospitalization and life insurance and family tuition support.

A report of the White House Council's Federal Laboratory Review panel also reported the following: "The inability of many Federal laboratories -- especially those under civil service constraints -- to attract, retain and motivate high-quality scientists is alarming. There are many reasons for this difficulty but the main one is noncompetitive pay and benefits compared with industry and universities. The National Institutes of Health has the largest difference between the Federal pay ceiling and the private sector earning power of specialized academic physicians."

As the above data indicates, it is unrealistic to expect notable scientists and physicians of stature in the biomedical research community to surrender tenure and lucrative benefits to accept an offer with NCI that is usually tens of thousands of dollars less than what they currently are earning. It is imperative that salary and compensation packages be established that will allow NCI to compete nationwide for the best available scientific talent

needed to carry out the mission of uncovering new knowledge that will lead to better health for everyone.

CLINICAL TRIAL ENROLLMENT

Question. In June 1988, NCI instituted a promotional campaign involving seminars, feature stories in the news media and making information on clinical trials more accessible to patients and physicians. Currently only about 25,000 patients a year enter NCI-sponsored clinical trials. The target is to enroll 50,000 new patients in trials each year by 1992. NCI will focus initially on enrolling more patients for studies of treatment for bladder cancer, colon cancer, rectal cancer and non-Hodgkin's lymphoma. These cancers were given priority because they affect large numbers of people or they are extremely responsive to the latest therapies.

How successful has NCI's effort been to increase patient participation in clinical trials?

Answer. A major impediment to progress in curing more cancer patients is that the necessary clinical investigation proceeds too slowly. For nearly every malignant disease, crucial studies accrue patients at an unacceptably slow rate, thus preventing the identification of new effective therapies in a timely and precise fashion. For the common adult malignancies only one-half of one percent to three percent of available patients are studied each year. Since definitive studies may require 1,000 to 3,000 patients, it has often taken a decade or more to complete the accrual phase of a study. With the dramatic expansion of basic and applied scientific research, there are an unprecedented number of research options.

Certain diseases have been selected in the attempt to achieve better clinical results more rapidly. Protocols for four potentially curable diseases -- adjuvant colon, rectum, bladder and advanced lymphoma have been designated as "High Priority Clinical Trials" of national importance and are targeted for special attention.

These studies are likely to provide important new information and to have an impact on national mortality rates. In order to succeed, there must be greater awareness of and enthusiasm for clinical trials by the general public and health care deliverers.

Efforts to increase accrual to designated "High Priority Clinical Trials" are progressing along two parallel tracks. The Office of Cancer Communications (OCC) is coordinating assessment and information campaigns for the lay and professional communities. The general public is being educated about clinical trials via print and electronic media. The various Cancer Information Services are also being targeted for OCC attention. The aim of this effort is to stimulate lay enthusiasm for volunteering for protocol studies.

The multi-disease, adult Cooperative Groups are expanding their clinical bases. More than 4,000 American Society of Clinical Oncology (ASCO) member physicians have been contacted and hundreds responded to the invitation to participate in the High Priority Trials. After screening, about 157 practices or institutions (new

and/or currently unfunded) were identified as promising resources. Four Groups are making special efforts to incorporate these new participants and have submitted detailed proposals and budgets to the Division of Cancer Treatment (DCT), NCI.

Estimates of activity from these proposals may be summarized as:

Group	New Institutions per Practices	New Patients/ per Year for Priority Trials
Cancer and Leukemia Group B	27	699
Eastern Cooperative Oncology Group	27	1,044
National Surgical Adjuvant Breast and Bowel Project	54	930
Southwestern Oncology Group	49	1,902
Total	157	4,575

The magnitude of impact of this accrual to adjuvant studies of patients with colon, rectum, and bladder cancer and for those with aggressive stage III-IV lymphomas will likely be substantial.

In the past year, DCT has continued to emphasize to the oncology community the need for rigorous prioritization of research questions needing clinical trial. The need to concentrate on the key issues in developmental therapy and to address them with trials of adequate size is evident.

Strategy meetings help provide an overview and prioritize national efforts in selected disease sites. Expert oncologists from the Cooperative Group and Cancer Centers meet at the National Cancer Institute to review ongoing clinical experiments and identify short-term priorities for research. The format of these meetings is to review the ongoing Cooperative Group clinical trials (with current estimates of accrual and projections of when studies would be completed) with discussion devoted to strategies for the next generation of clinical trials. Where appropriate, intergroup efforts are encouraged in order to achieve greater economy and statistical power. These meetings result in considerable exchange of information and capitalizing of collaborative research.

During fiscal year 1988, strategy meetings were held on adjuvant colon and rectum cancer, melanoma, and adjuvant breast cancer. During the next year, sessions are planned in esophageal and gastric cancer, brain tumors, non-small cell lung cancer, the adult acute leukemias, and ovary cancer.

With the input of the extramural community of cancer cooperative group investigators, the Cancer Therapy Evaluation Program has developed a set of guidelines for the conduct of studies involving two or more cooperative groups. In the past, intergroup studies have generally been developed and conducted in an informal manner. Many participants in intergroup studies have been frustrated by the lack of adequate quality control mechanisms, opportunities for input to study design, and regular monitoring

reports. At the request of the cooperative group chairmen, we have drafted a set of guidelines for the design and conduct of intergroup studies. After further input from cooperative group personnel (including statisticians, data managers, operations office staff, etc.), a final set of guidelines has been developed.

DCT is also working with group statisticians to determine, for several test intergroup studies, whether the amount of data collected can be substantially reduced without interfering with the quality or value of the research. Reduction in amount of data collection would both reduce costs and reduce the complexity of intergroup studies.

After many years of discussion and negotiation, DCT staff and representatives of the cooperative groups have succeeded in developing a set of common toxicity criteria for use in all investigational drug studies sponsored by DCT. Use of these criteria will be phased in, as time is necessary for groups and centers to alter their computerized databases and re-educate their staffs.

INTERLEUKIN-2

Question. In December 1985, there was extensive media coverage of a new experimental treatment involving the use a natural substances, interleukin-2 (IL-2), to stimulate the body's immune system against cancer. In December 1986 another report on the experimental IL-2 treatment was published along with an editorial challenging the work and severely criticizing the amount of attention the new treatment has received. Critics charged that the reports were premature, the treatment is very expensive, the side-effects too severe and the benefits are transient and uncertain. Recent modifications of the original treatment achieved dramatic success against skin cancer without as many severe side effects (Washington Post 12/22/88 and 3/30/88).

What is the current status of the new cancer treatment developed by Dr. Steven A. Rosenberg?

Answer. The latest published report by Dr. Steven Rosenberg and colleagues in the Surgery Branch of the National Cancer Institute described the activity of combination therapy with TIL cells (Tumor Infiltrating Lymphocytes), interleukin-2 (IL-2) and cyclophosphamide against melanoma. In that pilot trial, 20 patients with metastatic malignant melanoma were treated and 11 (55 percent) had shrinkage of measurable tumor by 50 percent or more. One patient had complete tumor eradication with this therapy. TIL cells are 50 to 100 times more potent in their antitumor activity in culture than lymphokine activated killer (LAK) cells and this increased activity seems to carry over to treatment of patients, as well. The 55 percent response rate seen in this pilot trial compares favorably with a 15 to 25 percent response rate obtained from previous clinical trials of adoptive immunotherapy with IL-2 +/- LAK cells in patients with malignant melanoma.

Related clinical trials currently being conducted by Dr. Rosenberg and colleagues include a combined cytokine trial of alpha-interferon and interleukin-2 which demonstrates significant

activity against kidney cancers and malignant melanoma, a study of interleukin-2 and tumor necrosis factor, a combination which has synergistic antitumor activity in cell culture, and a trial of TIL cells transduced with a marker gene to study the circulation and activity of these cells after stimulation and intravenous administration.

Question. What is the status of other immune system modulators, such as tumor necrosis factor and interferon, in the treatment of cancer?

Answer. Interferon has been extensively evaluated in patients with cancer. It was approved by the United States Food and Drug Administration for the treatment of hairy cell leukemia and the form of Kaposi's sarcoma that often occurs in patients with AIDS. In addition, it has been found to be an active agent in several tumor types where no other effective therapy has been found, such as malignant melanoma, renal cell cancer, carcinoid syndrome and functional endocrine tumors, and is active in several tumor types for which there are some effective palliative treatments but no curative therapy, such as myelogenous leukemia. The effects of interferon therapy in chronic myelogenous leukemia are particularly promising in that interferon induces responses in about 80 percent of patients and decreases the expression of the oncogene product that is felt to be important in the development of this form of leukemia. Conventional treatments for chronic myelogenous leukemia have rarely been found to affect expression of the oncogene. Interferon is currently undergoing clinical testing as a component of combined modality treatment programs. Already it has been demonstrated to prolong the remissions in patients with acute myeloblastic leukemia when employed after high-dose chemotherapy and allogeneic bone marrow transplantation. It appears to prolong remissions induced by chemotherapy in lymphoma and myeloma. There are likely to be a number of other clinical uses for interferon in the treatment of cancer.

Tumor necrosis factor is produced by monocytes and lymphocytes and is capable of killing certain types of tumors in experimental animals, especially when injected directly into tumor masses. In human trials, toxicity studies have established a maximum tolerated dose for tumor necrosis factor when given by injection into the vein or muscle. Animal studies suggest that its antitumor effects may be enhanced by a form of interferon (interferon-gamma) and it may have additive or synergistic effects when used together with chemotherapy.

In addition to interferon and tumor necrosis factor, a variety of recombinant human molecules are currently undergoing clinical trials in patients with cancer. They have boosting effects not only on bone marrow cells, but also on cells of the immune system capable of mediating antitumor effects. Two, GM-CSF and G-CSF, have been used alone and together with combination chemotherapy and both significantly reduce the bone marrow toxicity of chemotherapy. If patients are able to tolerate higher doses of chemotherapy as a result of the concomitant use of the colony-stimulating factors, it is likely that more patients will be cured of their tumors. In addition, these factors are likely to be useful alone and in combination to stimulate more potent immunological attacks on tumor

cells. Studies of the efficacy of these agents will begin after the current toxicity studies are completed.

REDUCTION IN CANCER MORTALITY

Question. The mortality rate from cancer continues to increase while the death rates from other major causes have been declining. In 1950, cancer caused 15 percent of all U.S. deaths; in 1985, 24 percent. Cardiovascular disease peaked in 1960, but since then heart disease and stroke have been decreasing as a cause of death. Although some of the increase in cancer mortality is due to the aging population, even the age-adjusted cancer mortality has been climbing. In 1985, NCI instituted a campaign to reduce cancer mortality by 50 percent by the year 2000. The campaign has targeted a reduction in the percentage of adults who smoke and dietary reductions in fat consumption and increases in fiber consumption as major aspects of the NCI's cancer prevention objectives. NCI estimates that these efforts will result in an eight to 15 percent reduction in cancer mortality by the year 2000. An increase in the transfer of treatment research results to practice is estimated to result in a 10 to 26 percent reduction in cancer mortality. Increases in screening for breast cancer and cervical cancer are estimated to reduce cancer mortality by an additional three percent.

What is the status of NCI's campaign to reduce cancer mortality by 50 percent by the year 2000?

Answer. Cancer research has made enormous strides in knowledge about cancer cause, development and prevention, about screening and detection, and about treatment -- all since the passage of the National Cancer Act in 1971. While many of these gains in knowledge are not yet at the clinical level, many others are, and there is a great deal that can be done now with current knowledge to reduce cancer mortality.

In 1985, The National Cancer Institute (NCI) developed, with the aid of expert committees, plans for the prevention and control of cancer that could cut the annual cancer death rate by as much as 25 to 50 percent by the year 2000. Achieving this goal, based on actual knowledge and judged by experts as reasonable, depends on taking action in prevention, screening and treatment.

Specifically, the following are targets or objectives to guide the cancer research and application programs toward the year 2000 goal. These objectives in smoking, diet, screening, and treatment include: reducing the percentage of adults who smoke to less than 15 percent; reducing dietary fat to less than 30 percent of total calories; increasing dietary fiber to 20 to 30 grams of fiber daily; increasing the percentage of women who are screened for breast and cervical cancer according to recommended guidelines; and increasing the application of state-of-the-art cancer treatments as well as the percentage of the public who have access to and participate in cancer clinical trials.

Achievement of these objectives requires cooperative effort by the government, specifically NCI and other agencies involved with health, industry, media, private voluntary and other health organizations, and individual citizens.

Today, as a consequence of clinical trials, new high tech methods of drug development, the elaboration of biological response modifiers, and more sophisticated radiotherapy, there are promising new treatments for almost all the major cancer killers of adults, including cancers of breast, colon, rectum, lung, bladder, prostate, kidney, melanoma, and bone and soft tissue sarcoma. Furthermore, treatments are both more effective and easier to tolerate. Consider that equal or better survival results can be obtained while preserving breasts, avoiding colostomies, avoiding impotence, and sparing limbs. There are also effective, often very new treatments for many of the common childhood cancers.

Progress in Incidence/Mortality/Survival

Mortality from many of the major cancers is declining, while for others there has been an increase. In general, the cancer outlook for younger Americans is improving. The total cancer mortality rate for those under age 55, 79 percent of the population, has decreased during 1950 to 1986. Lung cancer accounts for over 27 percent of the age-adjusted death rate and the large increases in this disease over the past 30 years are reflected in an increase in the overall cancer mortality rate which represents all cancer sites combined. Since 1950, lung cancer mortality has risen 241 percent, while the overall cancer mortality rate, including lung cancer, has risen only 9.1 percent. Lung cancer is highly associated with smoking, and a decline in smoking led in 1985 to decreases in the rate of new cases among both white and black males. The 1986 figure of 81.9 cases per 100,000 males is the lowest since 1980 when the rate was 84.3. In contrast, the trend in lung cancer incidence in females has been increasing when assessed as an overall age-adjusted rate.

Breast cancer is responsible for almost nine percent of all cancer deaths, and over 18 percent of cancer deaths in females. There has been an increase since 1983 in the recorded incidence of *in situ* breast cancer cases, which is due in all likelihood to increased screening activities both for women over 50 years and those under 50 years of age. Breast cancer mortality has remained essentially level among white females and increased about one percent per year among black females for the period 1973 to 1986. Women under 50 have experienced a distinct decline in mortality though 1983, but since 1984, there have been small increases in mortality. The pattern for women over 50 has been one of no change through the 70s, after which each succeeding year of the 80s shows a small increase. The reasons for the changes are not clear, however, clinical trials have shown that screening can reduce breast cancer mortality at least 30 percent. The lack of a large decline in mortality strongly suggests insufficient screening.

Over the most recent five-year time period for which we have data, 1982 to 1986, many cancers continue to show encouraging decreases in mortality and/or increases in survival due to treatment advances and/or earlier detection. For example, colon and rectal cancer, had a 2.5 percent decline in mortality. Other declines over the same recent period in mortality are: testicular cancer, 14.9 percent; Hodgkin's disease, 10.2 percent; and cervical cancer, 6.8 percent. Stomach cancer mortality, 13,900 deaths annually, the

eighth leading cause of cancer deaths continues to decline significantly. The decline in stomach cancer mortality between 1982 and 1986 has been over 7.1 percent, with improvement resting on dietary changes and advances in diagnostics.

Other cancers showing major decreases in mortality include cancer of the uterine corpus, the most common of the gynecologic tumors, accounting for about 34,000 new cases every year and 4,000 deaths. The five-year survival rate is over 80 percent and over 90 percent for cases diagnosed in a localized state -- mortality has fallen by 6.5 percent from 1982 to 1986. Bladder cancer mortality has decreased by 7.3 percent over the same time period.

Yet, some cancers continue to show an increase in mortality due to an increase in the rate of new cases. For example, there has been a marked increase in non-Hodgkin's lymphoma incidence -- 11.5 percent between 1982 and 1986, and mortality has increased by eight percent. The reasons for the increases are not known. The mortality rate between 1982 and 1986 from melanoma has also been increasing -- at about 1.1 percent per year for a total increase of over 3.4 percent. The increase is thought to be due largely from lifestyle changes that have brought an increase in sun exposure.

Specific Targeted Areas for Cancer Prevention and Control

Smoking: Smoking is responsible for 30 percent of all cancer mortality -- over 150,000 deaths per year. Recent smoking data show that 32 percent of adult males, aged 20 and over, are current smokers while 27 percent of adult females are current smokers. In 1965, 52.4 percent of adult males and 34 percent of females were smokers.

Diet: Recent analyses indicate that over the past seven to eight years there have not been major changes in the fat intake patterns in the United States. The Continuing Survey of Food Intakes by Individuals conducted by the United State Department of Agriculture (USDA) showed essentially no difference from 1985 to 1986, with the percentage of calories attributable to fat at approximately 37 percent. The same USDA survey shows essentially no change in intake of the amount of dietary fiber (11.8 grams in 1985 and 11.7 grams in 1986).

Screening: Although national data were available to set the cancer control objectives for Pap test and breast physical examination, similar high quality data did not exist for mammography. Previous studies indicated mammographic screening has occurred for approximately 15 to 20 percent of all women and occurs regularly for a much smaller proportion. Recent 1987 data from the National Health Interview Survey Cancer Control Supplement indicate that breast physical exam is a familiar and commonly used procedure. Less than 10 percent of women aged 40 and over have never heard of a breast exam and 44 percent have had one in the past year for screening purposes. Mammography is less well known and much less common. Some 16 percent of women aged 40 and over have never heard of this exam and only 17 percent reported being screened in the past year. Screening for cervical cancer is at a high level, (about 73 percent), but there are areas of the country which have extreme cervical cancer mortality and should be targeted for cancer control

programs. Cervical cancer mortality among black females is 7.6 deaths per hundred thousand compared to cervical cancer rates among white females 2.7 deaths per hundred thousand. Such differentials provide the rationale for targeted NCI cancer control efforts.

TABLE 1

CIGARETTE SMOKING PREVALENCE AMONG PERSONS 20 YEARS OF AGE AND OVER

UNITED STATES, 1965, 1976, 1980, 1985, AND 1987

By Sex and Age

Cigarette Smoking Prevalence (%)*

Sex/Age	1965	1976	1980**	1985	1987
Males:					
20+ years	52.4	41.9	38.3	33.2	31.7
20-24 years	59.2	45.9	39.7	31.0	31.1
25-34 years	60.7	48.5	43.1	38.2	34.8
35-44 years	58.2	47.6	42.6	37.6	36.6
45-64 years	51.9	41.3	40.8	33.4	33.5
65+ years	28.5	23.0	17.9	19.6	17.2
Females:					
20+ years	34.1	32.0	29.4	28.0	26.8
20-24 years	41.9	34.2	32.7	32.5	28.1
25-34 years	43.7	37.5	31.6	32.0	31.8
35-44 years	43.7	38.2	34.9	31.5	29.5
45-64 years	32.0	34.8	30.8	29.9	28.6
65+ years	9.6	12.8	16.8	13.5	13.7

* A smoker is a person who had smoked at least 100 cigarettes and who smoked at the time of the survey; it includes occasional smokers. The base of percent excludes persons with unknown smoking status.

** Based on data for the last six months of 1980.

Source: National Health Interview Surveys, 1965, 1976, 1980, 1985, and 1987.

TABLE 2

WOMEN, AGES 18 AND OVER

SCREENING PRACTICE

	Practice (percent reporting)		
	Pap Smear 1/	Breast (Physical) 2/	Mammography 2/
Within past year	48	44	17
1-3 years ago	17	15	6
More than 3 years ago	16	15	7
Had for problem	8	7	7
Never had	7	10	48
Never heard of	4	9	16

[1]Women with hysterectomy excluded; ages 18 and above.

[2]Women ages 40 and above.

Source: National Health Interview Surveys, 1987

CANCER PREVENTION

Question. The budget for cancer prevention and control has declined since 1980, although the total NIH budget has risen more than 50 percent. NIH and NCI have been accused of emphasizing the potential of laboratory and clinical research at the expense of efforts on prevention. Critics point to mortality rates which, when adjusted for changes in age distributions and population size, have increased by 8.7 percent from 1962 to 1982. NCI has received considerable criticism on this issue, most recently in a March 1987 GAO report. A change in emphasis from treatment research to prevention is often suggested.

What are NCI's objectives in the area of cancer prevention?

Answer. Recent review of mortality data indicates that overall cancer mortality in the U.S. may be on the verge of a decline. Scientists have noted a decline in cancer mortality among middle-aged and younger Americans. Researchers state that the decline in cancer deaths among those younger than 65 appears to reflect a growing emphasis during the last 20 years in preventive measures -- such as increased eating of fresh vegetables, less eating of fat and less smoking. Since the decline may stem from a gradual change in lifestyle, the overall decline in cancer death rates may also continue as younger age groups enter the cancer-prone years.

To continue this downward trend in cancer mortality rates NCI activities in cancer prevention will be carried out across the continuum, from basic research through clinical trials and intervention research, to broad dissemination and application of the research results. Basic research covers a broad range of approaches with emphasis on the mechanisms of action of chemical and physical carcinogens and the development of methods to prevent their actions. For example, NCI's Laboratory of Chemoprevention focuses its research on the effects of retinoids on tumor development and on the

interactions of retinoids, growth factors and oncogenes in normal development and in the neoplastic process. One of the growth factors they are studying, transforming growth factor beta (TGF-beta), has been shown to play an essential role in the regulation of cellular growth and differentiation. Studies on the functions and biochemical mechanisms of this growth factor are being carried out and efforts are now underway to mutate TGF-beta in order to develop antagonists to its biological actions which could thus serve as chemopreventive substances.

Other basic research activities in prevention are focused on the experimental inhibition of carcinogenesis caused by chemical, physical, and biological agents. Efforts are being directed at the identification, development, and testing of agents intended to inhibit carcinogenesis. Areas of prime interest include mechanisms of action of candidate preventive agents, binding proteins and receptors, structure-function relationships, and the experimental use of combinations of preventive agents. Of special interest are pharmacokinetic investigations of promising agents for optimizing dose and delivery schedules in chemoprevention and for deriving a better understanding of structure-activity relationships for efficacy and toxicity. In addition, studies in animals are underway in which the efficacy of the chemopreventive agents is being assessed in relation to those carcinogens, cocarcinogens, and promoters against which activity exists, organ sites at which inhibition is possible, and the stage of the carcinogenic process at which agents possess activity.

A new approach to cancer prevention and the development of new chemopreventive agents, National Collaborative Chemoprevention Projects, has been initiated and will be emphasized. These collaborative projects are designed to acquire basic knowledge of biological systems for anticarcinogenesis. A multidisciplinary approach is employed to derive new insights into practical means to prevent the carcinogenesis process and to translate this knowledge rapidly into new chemopreventive entities with known ranges of efficacy and defined pharmacologic/toxicologic properties.

NCI epidemiologic studies will continue to emphasize case-control and cohort studies aimed at evaluating key hypotheses in cancer etiology with the view that cancer prevention is more feasible when the etiologic agent is known. Whenever possible, laboratory procedures are incorporated into the epidemiologic studies to clarify exposures, preclinical responses, and mechanisms of carcinogenesis.

New priorities in cancer prevention research also include an emphasis on the areas of diet and chemoprevention. These initiatives are necessary to greatly expand the current knowledge base in these areas which are thought to hold great potential for cancer prevention. Initiatives in this area include a proposal to increase the physical resources and staff of the Cancer Nutrition Research Laboratory and plans to greatly expand laboratory and clinical studies of a wide variety and nutritional and other substances with cancer preventive potential. Substantial efforts are being directed at testing current hypotheses and generating additional testable hypotheses regarding the contribution of dietary factors to human cancer. Dietary exposures currently being assessed

include consumption of specific food groups and food items such as meat, fruits, and vegetables; ethnic dishes and coffee; macronutrient and micronutrient intake such as fat, vitamin A, carotenoids, vitamin C, folacin, and trace minerals; general nutritional status; anthropometry; biochemical indices such as serum cholesterol and serum beta-carotene; and storage and cooking practices. Cancers being studied include those of the colon, rectum, breast, lung, cervix, pancreas, stomach, and larynx. A variety of field investigations have revealed evidence of diminished risks for a number of malignancies associated with higher levels of intake of fruits, vegetables, and plants in the allium class, e.g., garlic, chives, onions, etc., and various nutrient indices, including carotene and vitamin C. These relationships have been noted in several investigations of lung cancer, stomach cancer, laryngeal cancer, pancreatic cancer, and mesothelioma.

A large-scale, collaborative intervention trial will continue in Linxian, China, an area where the incidence of esophageal carcinoma is the highest in the world. One component of the trial focuses on 3,000 persons with esophageal dysplasia. Another involves 30,000 villagers from the general high-risk population. Participants have been randomly assigned to one of several groups to receive different combinations of vitamins and minerals or placebo over a five-year period. The study will evaluate whether certain groups of vitamins and minerals can inhibit late-stage progression to cancer in a high-risk population with multiple micronutrient deficiencies, and may have considerable implications for the effectiveness of nutritional intervention programs in lowering cancer incidence worldwide.

"Cancer Control Objectives for the Nation: 1985-2000," published by NCI in 1986, reported research that showed the two areas with the largest potential to reduce cancer deaths are the prevention and cessation of tobacco use and dietary modification. Consistent with these priorities, NCI is projecting major initiatives in these areas for 1990 and beyond, as documented in "Plans and Resources," a report written in response to a request from the Senate Appropriations Committee.

NCI is conducting and planning two broadly-based, community-oriented tobacco use prevention and cessation programs, the Community-Based Intervention Trial for Heavy Smokers (COMMIT) and American Stop Smoking Intervention Study (ASSIST). These programs represent a major shift in NCI's smoking and tobacco research from efficacy trials toward implementation and applications.

FEDERAL FUNDING OF CANCER RESEARCH

Question. Can you put any dollar figure on the amount of Federally-funded cancer research conducted outside of NCI, both by other Institutes of NIH and by other Federal agencies.

Answer. The most recent data describing the amount of Federally-funded cancer research conducted outside of NCI both by other Institutes and by other Federal agencies was compiled in fiscal year 1984. NCI and non-NCI resources for cancer research and control each comprised half the estimated total national resources for cancer research and control of $2.2 billion.

MINORITIES

Question. Doctor, I understand that there is quite a differential between the incidence and mortality from cancer as experienced by blacks and whites. Can you tell us what you plan to do about this differential? How much do you currently spend in this area?

Answer. Some very troubling trends have been noted in cancer incidence and mortality among black Americans over the past three decades. Both the overall cancer incidence rate and death rate have remained higher for blacks than whites, and these differences are becoming more pronounced. The overall cancer incidence rate for blacks has gone up 27 percent compared to an increase of 12 percent during this period for whites. Cancer death rates have also increased disproportionally, rising 50 percent among blacks compared to 10 percent for whites. Blacks have experienced a significantly higher increase in incidence and mortality rates from lung, colorectal, prostate, and esophageal carcinomas than whites. Even in cancers where the incidence has decreased, such as cancer of the uterine cervix, the decrease has been less pronounced in blacks than it has been for whites.

Cancer survival is closely related to the stage of disease; that is, the extent to which the cancer has spread at the time of diagnosis. Those cancers detected before there has been any distant spread are much more amenable to treatment and cure than those detected only after the cancer has metastasized. Here, too, a discrepancy is seen between the races; 39 percent of whites are diagnosed while their cancers are still localized whereas only 30 percent of blacks have their cancers detected at this early, and favorable, stage. Obviously, public awareness of the value of self-examination and the accessibility of screening tests impact on these figures. A 1986 poll revealed that while 92 percent of white women knew of the Pap test and 85 percent had had the test at some time, only 76 percent of black women knew of it and 70 percent had had it. For proctoscopic exams, 68 percent of the white population were aware of the procedure and 38 percent had had it at some time, while for blacks, only 41 percent were aware of it and 21 percent had had it.

We need to know why these differences occur. We need to reexamine our efforts at informing the public on the importance of early screening tests and make sure that we are reaching all of our citizens. We need to develop ways of providing those screening tests to a larger percentage of our citizens, understanding that some do not receive these tests because of financial constraints or lack of access to screening facilities. We must examine this problem with the same degree of precision and commitment that we apply to all cancer research. Only through such efforts will we be able to identify, and resolve, the disturbing differences we currently see in cancer incidence and mortality between blacks and whites.

An example of a step recently taken is the formation of a Breast Cancer Working Group to attempt to determine the reasons for the increased aggressiveness of breast cancer in black women. A

major emphasis will be to analyze potential molecular markers, such as increased activity of oncogenes and growth factors to determine whether these may account for the poor prognosis of breast cancer in black women.

Recognizing the critical need to give special attention to the disproportionate burden of cancer borne by black Americans and the important task of delivering health promotion messages to counter the practice of targeting this community for activities which promote the use of products that are known to have serious health consequences, the National Cancer Advisory Board (NCAB) instituted the National Black Leadership Initiative on Cancer. Dr. Louis Sullivan, who until his appointment to the Cabinet was a member of the Board, chaired the Initiative whose creation he stimulated, and deserves great credit for having set the stage for better prevention, diagnosis and treatment of cancer in the black community. Dr. Sullivan recognized that to really make a change, a program had to be created and integrated within the community.

Fundamental to this initiative is the mobilization of individuals who are committed to achieving a high level of cancer prevention awareness among black Americans. The message at the heart of this effort is that cancer is, to a great extent, preventable. And prevention and control of cancer in minorities will depend critically on achieving marked changes in avoidance of tobacco products, adoption of high fiber-low fat diets, involvement in screening and early detection activities, and gaining access to state-of-the-art care and treatment.

As a first step in mobilizing a significant part of the minority community in this effort, the NCI will recruit and support a regional coordinator in each of the six cities which served as the location for the regional meetings of the National Black Leadership Initiative on Cancer. These meetings, which took place over the course of the past year, in Atlanta, Los Angeles, Chicago, New York, Washington and Houston, brought together black leaders from many fields -- academia, clergy, medicine, business, public health, the media, state and local legislatures -- to develop strategies for initiating or enhancing cancer control and prevention activities in the black communities of the respective regions. The regional coordinators will represent an NCI presence in these communities and will serve a liaison role in identifying community resources, facilitating their most effective utilization, as well as assisting communities in obtaining and optimizing support from NCI in implementing local cancer prevention and intervention programs.

The second part of this community-based NCI plan is to actuate, as quickly as possible, a concept for grant-supported demonstration centers in areas where minorities live. An essential criterion for these awards is for the grantee institution to have demonstrated the ability to work collaboratively with the minority community in programs of education and health promotion. The thesis is that reduction in mortality among minority populations at high risk for specific cancers should be achievable in those cases where effective therapeutic interventions exist if improved access to treatment can be assured; and the stage shifts as diagnosis can be expected to accompany an increase in screening and early detection programs if these are conducted in high density minority population areas. It is expected that at least one such award will be made by 1990.

Other initiatives include:

- The development of programs oriented toward the needs of Hispanic communities modeled on similar and ongoing efforts that are directed toward black and Native American communities.

- The continuation of 13 trials on smoking prevention and cessation addressed to the special needs of black and Hispanic communities. NCI will continue to work with a network of black and Hispanic leaders to disseminate the most effective smoking prevention and cessation strategies as results of these trials become available. New initiatives are also planned which address the needs of Native Americans and Pacific Islanders in this area.

- Complementary to the planned expansion of the Community Clinical Oncology Program, a special effort is proposed to serve predominantly minority communities. This program would enhance current NCI efforts designed to close the gap in survival between white and black cancer patients. This initiative would enable academic and community oncologists with large minority populations to gain enhanced access to state-of-the-art cancer management through participation in treatment and cancer control clinical trials. Reflecting our high priority toward addressing minority concerns, this program has already received initial funding and it is anticipated that this financial commitment will continue through fiscal year 1990 and beyond.

- NCI has an ongoing program designed to determine how to increase the use of Pap smears and follow-up medical treatment for low income and black women with early stage cervical cancer. NCI also plans to continue and expand a number of programs designed to enhance the capacity of state and local public health departments to administer cancer screening programs to low income women.

- Expansion of the Surveillance, Epidemiology and End Results Program (SEER) has been proposed in order to provide more adequate statistical coverage of minority populations.

The total fiscal year 1990 estimate for NCI-sponsored minority and related initiatives is $34,466,000. Of this amount approximately $20 million is for targeted activities.

ADJUVANT THERAPY

Question. We've heard much recently about adjuvant therapy. A treatment with chemotherapy in addition to radiation or surgery appears to be successful. Can you update us on this therapy, particularly related to breast and colon cancer?

Answer. Adjuvant therapy trials are currently being conducted for both colon and breast cancer. A description of these trials follows:

- <u>Large Bowel Cancer Adjuvant Therapy</u>

The North Central Cancer Treatment Group (NCCTG) study of

levamisole + 5-FU as adjuvant therapy for postsurgery colon cancer patients has been completed and has shown a clear advantage for the treated Dukes' C1 patients as compared with those who did not receive chemotherapy. A national intergroup study has recently been completed to confirm these results and accrued 1,200 patients. The data quality is excellent, and answers to disease-free survival questions will be available in another one to two years. A National Surgical Adjuvant Breast and Bowel Project (NSABP) study demonstrated the superiority of the combination MeCCNU oncovin, 5-FU (MOF) chemotherapy to no postsurgical treatment. New studies in colon cancer will examine the efficacy of 5-FU + folinic acid. In a series of three trials initiated within the last year, the therapeutic role of 5-FU/leucovorin will be defined and compared with previously determined standard therapy. In addition, a trial in rectal cancer has shown that combining radiation and chemotherapy is superior to radiotherapy alone in the postsurgical setting. A new trial examines the potential benefit of continuous infusion 5-FU chemotherapy to maximize radiosensitization and whether MeCCNU can be deleted as a component of such treatment, thereby reducing the immediate toxicity as well as the possibility of secondary leukemia.

- Breast Cancer (Adjuvant)

In the past year, the most significant new information to come from Cooperative Group clinical trials in breast cancer were studies of patients whose disease was limited to the breast and had not spread to any local lymph node, the so-called "node-negative" patients. Two studies were the first U.S. trials comparing adjuvant therapy without additional treatment following surgery. Disease-free survival advantage has demonstrated for treatment compared to no treatment. These results were published in an NCI Clinical Alert in May 1988 because of their potential public health implications. Other ongoing clinical trials in breast cancer include:

-- A trial is designed to test the hypothesis of dose intensity of chemotherapy in the adjuvant therapy of women with node-positive breast cancer. Patients are randomized to one of three dose levels of the combination of cyclophosphamide, adriamycin and 5-FU. The duration of treatment varies among the three treatment groups so that the planned total dose of the three drugs is the same for each group. Approximately 1,200 patients have been entered on the study, which should complete accrual by the end of 1989.

-- A study opened in October, 1988, and compares preoperative chemotherapy in patients with primary breast cancer. Patients are diagnosed by fine needle aspiration and then randomized either to four cycles of adriamycin and cyclophosphamide before surgery or to initial surgery followed by the same chemotherapy.

-- A further trial compares chemotherapy with methotrexate and 5-FU (MF) with or without cyclophosphamide in women with node-negative breast cancer whose tumors have poor estrogen receptor content. This study also opened in October, 1988.

-- Another ongoing trial includes those patients with node-negative breast cancer whose tumors are positive for estrogen receptor. It compares the use of tamoxifen alone with tamoxifen plus either methotrexate and 5-FU (MF) or the same two drugs plus

cyclophosphamide. The objective is to evaluate whether chemoendocrine therapy is superior to endocrine therapy with tamoxifen alone and whether cyclophosphamide adds anything to the MF combination. The trial began in October, 1988.

SUPERCOMPUTER

Question. Your By-Pass budget requests funds for a special initiative for an upgrade of the supercomputer located at the Frederick Facility. We're aware of the successes and impact of the existing computer on biomedical research and we also realize that the technology in this field is moving and changing rapidly. In your opinion, what would be the total cost to upgrade the operation? Would it be utilized in the proposed project to map and sequence the human genome?

Answer. As you have stated, in the relatively short time the Advanced Scientific Computing Laboratory (ASCL) has been operational, the success of applying modern supercomputer methods to biomedical science has become apparent. The existing Cray X-MP 24 is averaging nearly 5,000 jobs per month, leaving little room for additional workload. Because there is every reason to expect that major growth in the computational needs of biomedicine will continue, a machine with more processors and vastly increased memory capability would be extremely valuable. It is anticipated that the cost to procure an expanded memory, multiprocessor supercomputer with appropriate peripherals would cost approximately $25 million. That would permit development of techniques in areas of drug design, molecular structure analysis, analysis of x-ray data, and modeling of complex biological processes that are not possible at present. While the supercomputer will not play a direct role in the human genome project, it will be important for some of the complex analyses that will be possible as a result of the new data that will be generated.

CLINICAL TRIALS

Question. What exciting results have been found this year in the clinical trials area, especially in the hard to treat cancers, e.g., colorectal cancer and/or prostate cancer?

Answer. Recent results of clinical trials revealed the following:

In prostate cancer, its optimal management remains an area of great controversy. The therapeutic options are radical prostatectomy or radical radiotherapy. One small randomized trial comparing the two approaches has been reported, which suggested that surgery provided superior results to radiotherapy. The results of that study have not been strongly embraced because of its small size and because of the nonstandard way in which the analysis of the study was reported. Thus, the question remains open. The Institute is supporting a study that will satisfactorily answer the question.

The optimal hormonal management of patients with newly diagnosed metastatic prostate cancer remains an area needing further study. A recently conducted NCI-sponsored clinical trial showed that combination castration plus antiandrogen is superior to medical

castration. A confirmatory trial that will employ surgical castration with or without antiandrogen therapy is being planned.

In breast cancer, one of the most important concepts that needs to be tested is the value of dose intensive regimens in the adjuvant setting. It is anticipated that the colony stimulating factors (CSFs) will allow greater dose intensive regimens to be safely administered. Pilot studies are being conducted at several institutions to identify a dose and schedule of CSF plus chemotherapy that can be used in the adjuvant setting.

Adjuvant therapy has recently been shown to improve substantially the disease-free survival of node-negative breast cancer patients compared with women receiving no adjuvant therapy. A study will seek to determine whether adriamycin is superior to methotrexate for women with node-negative breast cancer.

In postmenopausal patients with hormone receptor-positive node-positive breast cancer, a study comparing adjuvant tamoxifen alone with CAF followed by tamoxifen is planned. In all previous trials comparing endocrine therapy alone with chemoendocrine therapy, the result of which have failed to consistently show a benefit of chemotherapy, the chemotherapy has been given concurrently with tamoxifen. As tamoxifen may have a protective effect against chemotherapy, this trial will evaluate whether that potential protective effect is clinically meaningful.

The National Surgical Adjuvant Breast and Bowel Project (NSABP) plans to study women with node-negative breast cancer whose primary tumors are defined as being clinically occult, i.e., those identified by mammography that are too small for quantitative estrogen receptors or those that are primarily intraductal but with areas of microinvasion. All the patients on this trial are to undergo lumpectomy followed by radiation plus tamoxifen, radiation plus placebo, or tamoxifen alone without radiation.

Over the past few decades, there have been few advances in the therapy of patients with advanced stage chronic lymphocytic leukemia (CLL). However, two cytotoxic agents have been recently demonstrated to be active in this disorder -- 2'-deoxycoformycin (DCF) and fludarabine. DCF is associated with a 25 percent response rate and fludarabine up to a 50 percent response rate in previously treated patients. More important, a number of these responses are complete. A strategy meeting was convened by NCI staff to discuss national clinical trials using these agents. The results were gratifying in that the Cooperative Groups and major centers developed a set of common eligibility, response, and toxicity criteria with which to pursue trials with these agents. A number of Phase I and II studies are planned combining these two drugs with each other or with conventional CLL regimens. The objective will be a national collaborative Phase III trial comparing several of these regimens with standard therapy.

PROTON BEAM (HEAVY PARTICLE) THERAPY

Question. Doctor, I understand that you have supported research at Massachusetts General Hospital on what is called "proton beam therapy" for a number of years now. Can you tell us what this therapy is and what your future plans for it are?

Answer. Proton beam therapy refers to a relatively new type of therapeutic radiation which uses heavy particles, rather than traditional x-rays, to destroy cancer cells. A group of physicians, physicists, and engineers from the Massachusetts General Hospital (MGH), the Massachusetts Eye and Ear Infirmary, and the Harvard Cyclotron Laboratory have been conducting clinical trials in proton beam therapy since 1974 with NCI support. These trials have demonstrated effective local control in a number of tumors, including base of skull chordoma/chondrosarcoma, incompletely resected soft tissue sarcomas, uveal melanoma, and several other tumor types.

The proton beam facility used for these studies was originally designed for physics research and was subsequently converted to a medical treatment facility. Because it is over 30 years old, MGH researchers have approached the NCI to explore the possibility of funds being made available to purchase a new proton beam accelerator to conduct further clinical trials. A report was presented to the NCI earlier this year that summarized the achievements of the MGH proton beam researchers and estimated the level of support necessary to purchase a new cyclotron to conduct expanded clinical trials.

NCI policy regarding particle beam therapy was first formulated at a time when several types of particles, both neutrons and protons, were being evaluated for clinical application. Because of the construction and maintenance costs for the equipment associated with proton beam therapy, it was decided to pursue a sequential approach in the development of this treatment modality. Owing to the preliminary results of clinical trials, the technology available, and the relatively less expensive neutron equipment required, a decision was made to pursue neutron therapy first. It was felt that if neutron therapy was proven to be effective, then the more costly clinical therapy facilities and equipment for proton beam therapy would be considered.

At this time, NCI will continue to support existing grants for proton beam research but no funds are currently available for the purchase of a new cyclotron or the construction of a new facility for the conduct of clinical trials using proton beam therapy. Therefore, while ongoing proton therapy research will continue to be supported, no new initiatives in this area are currently being planned.

LUNG CANCER RESEARCH DEVELOPMENTS

Question. We are all concerned about lung cancer. Can you tell us what the latest developments in lung cancer research are?

Answer. One of the biggest problems we face with lung cancer is that there are few symptoms associated with the early stages of the disease. By the time symptoms develop, in many cases, the cancer has already spread beyond the lung and is virtually incurable. Several years ago, researchers from a number of cancer centers joined together to form the Lung Cancer Study Group (LCSC) whereby their combined resources and expertise would be used to facilitate progress against lung cancer.

Through the use of monoclonal antibodies -- small molecules that can recognize specific proteins on the surface of a cell in a "lock-and-key" fashion -- LCSC researchers developed a test which detected lung cancers at a very early, and potentially curable, stage of development. In this retrospective study, the monoclonal antibody had a 91 percent accuracy in predicting which patients developed lung cancer over the subsequent two years, and had a 70 percent accuracy in predicting lung cancers four years ahead of time. Researchers have now embarked upon a prospective trial to look at early diagnostic and therapeutic intervention in this group of patients in an attempt to detect, treat, and potentially cure people with asymptomatic, early stage lung cancer.

NCI researchers have also found that small cell lung cancer appears to occur as the culmination of a sequence of about 10 to 15 genetic alterations that occur in the cell over a long period of time. This may explain why lung cancer develops slowly, after years of exposure to carcinogens such as cigarette smoke or asbestos. These latest findings may make it possible to identify those individuals who are particularly at risk for the development of lung cancer and who should therefore avoid exposure to these carcinogens. Such studies may also lead to future testing for the presence of these genetic lesions in the normal bronchial cells of cigarette smokers to identify those persons with cells that are already on the way to becoming cancerous and who may benefit from cancer therapy.

Another exciting event in lung cancer research over the past year has been the development of more effective therapy for small cell lung cancer. Even when detected at an early stage, only 50 percent of patients survive one year with standard chemotherapy, and only 15 to 20 percent will be alive five years after diagnosis. Researchers at the NCI-Navy Medical Oncology Branch have conducted a pilot study of simultaneous aggressive chemotherapy and radiation therapy in patients with limited stage small cell lung cancer. All 23 patients responded with at least a 50 percent reduction in the size of their tumor, and 89 percent had all evidence of their cancer disappear (i.e., went into complete remission). Although the median follow-up is 13 months, the actuarial survival is 95 percent at one year and 83 percent at two years; figures are considerably above those obtained with standard therapy. Efforts will now be turned to confirming these results in a large-scale clinical trial at multiple cancer centers around the country and building on these results to further improve the survival in small cell lung cancer.

RADIATION-INDUCED CANCER RISK

Question. What is the NCI doing in regards to reports of increased cancer mortality in populations living around nuclear facilities?

Answer. The NCI is conducting a study of cancer deaths in the vicinity of nuclear facilities in the United States. The study was initiated in 1987 because of American public health concerns, and after a British survey of cancer mortality in areas around nuclear installations in the United Kingdom showed an excess number of childhood leukemia deaths. Results from other smaller surveys of cancer deaths around nuclear facilities from the U.S. and U.K. have

yielded conflicting results. Only nuclear facilities that are or once were in operation, and went into service before 1982, are included in the study -- a total of 61 sites. All 52 commercial nuclear power facilities in the United States that started before 1982 are included in the survey. In addition to the commercial nuclear power facilities, nine Department of Energy (DOE) nuclear installations have been included in the study. The DOE facilities do not generate electrical power for commercial use. In the British survey, the excess of childhood leukemia was found mainly around nuclear installations that were involved in the enrichment, fabrication, and reprocessing of nuclear fuel, or in research and development of nuclear weapons and not for generation of electricity. The DOE facilities are included in the NCI study because they are similar to the British facilities which were previously surveyed. The DOE installations have been operating since about 1943, while the first commercial nuclear power plant began operation in 1957. NCI investigators will analyze the nine DOE facilities both as part of the total group of nuclear facilities and as a separate group. The study includes facilities about which questions have been raised, such as Three Mile Island and Pilgrim.

The study will examine mortality from all forms of cancer, as well as from nine specific types, including leukemia, multiple myeloma, and cancers of the breast, lung, and digestive system. Counties with nuclear facilities will be compared with ones that do not have such facilities and are located at some distance from any facility. Any other county that does not have a nuclear facility but is adjacent to a county that does, is within 10 mile of the nuclear facility, and contains one-fifth of the land in the 10 mile radius of the nuclear facility is also included. In total, 113 counties have been chosen as case counties. Counties with nuclear facilities will be compared with one that do not have such facilities and are located at some distance from any facility. Comparison counties have been matched on such factors as racial composition, educational level, population size, average family income, and urbanization. Although one motivation for the study was concern about possible risks from ionizing radiation, other significant risks, such as those that may result from leaks of toxic chemicals, will also be evaluated.

In addition to internal review, the design of the study (protocol) was evaluated by an expert team of non-government scientists. Because of the importance of clarifying any potential health hazards associated with living near nuclear facilities, a special advisory group has been established to help evaluate the study results. The advisory group consists of selected members of NCI's Division of Cancer Etiology's Board of Scientific Counselors and other non-governmental scientists with expertise in this area. In addition to the normal NCI internal peer-review requirements for approval of scientific studies before they are submitted to journals for publication, the advisory group will review and comment upon the scientific validity of the final report.

This mortality study is possible because NCI has acquired county data on all deaths, by cause, from the year 1950 forward from the National Center for Health Statistics. The data are now being analyzed and a final report is expected by the end of 1989. It is only an initial step in evaluating the possible hazards of living

near nuclear facilities. This study will complement other ongoing studies and planned investigations conducted by the Center for Disease Control, various state health departments, and other groups.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Question. Doctor, what accomplishments has the NCI made in regards to new therapies for AIDS in adults and children?

Answer. Over the past year, the development of treatment for AIDS and related disorders has continued to be a high priority in the Clinical Oncology Program (COP) located in the Division of Cancer Treatment, NCI. The COP was one of the first to initiate in vitro testing of agents for their ability to inhibit the replication of the AIDS virus and was one of the first treatment centers to initiate experimental drug therapy in patients with AIDS directed at inhibiting the AIDS virus (HIV).

The COP played a major role in the recent development of azidothymidine (AZT), which is the only approved drug for the treatment of adults with AIDS. The drug was initially found to block infection of human lymphocytes in cell culture by HIV in a National Cancer Institute (NCI) laboratory in February 1985. The first clinical trial of AZT started in July 1985 and found that AZT was tolerated in AIDS patients, was able to penetrate into the brain, and caused clinical and immunological improvements in patients with AIDS and related disorders. This information was used as a basis to institute a larger trial of AZT which confirmed that it improved the survival and overall condition of patients with AIDS. Based on the results of this trial, AZT became the first and only approved drug for the treatment of severe anti-HIV infection. In a subsequent study at the NCI, it was found that AZT could improve certain brain dysfunctions caused by the HIV virus. Thus, these types of studies led to the establishment of the principle that development of therapy for patients with AIDS is an obtainable goal and that even certain AIDS induced brain dysfunctions are amendable to therapy.

Pediatric AIDS is now recognized as an important medical problem in this country and continues to be a major source of newly infected patients. Pediatric AIDS is clinically a different disease from that found in adults, and children often display different toxicities to drugs. The NCI has been conducting a trial of AZT in children with AIDS and the early results indicate that the drug is well-tolerated and results in clinical improvements. Specifically, brain dysfunction, a common problem in pediatric AIDS, shows marked improvement with AZT and has been one of the most striking findings in this trial.

Another major thrust of the NCI clinical program has been the development of other drugs related to AZT, for the treatment of AIDS. Specifically, 2'-3'-dideoxycytidine (ddC) has been shown in cell culture to be more potent than AZT and in early clinical trials has demonstrated penetration into the brain and improvements in the immune systems of patients with AIDS. This trial also established that a reversible, painful disorder of nerves occurs at high doses of ddC. It is important to note that this toxicity does not occur with AZT, suggesting that if ddC and AZT were used together, it may

be possible to attain a sustained effect against HIV with less toxicity from either agent. A trial is presently being conducted at the NCI, in which AZT and ddC are given on alternate weeks. Preliminary results from this trial indicate that patients can tolerate this regimen for over six months without developing significant toxicity from either drug. The NCI is also investigating another related drug called, dideoxyinosine (ddI) and early Phase I clinical trials show that this agent has very low toxicity and has produced significant improvements in patients' immune systems. Both ddC and ddI will soon be entering larger, multicenter trials for evaluation as anti-AIDS therapies.

The NCI is also interested in looking at combinations of AZT in conjunction with factors which stimulate bone marrow cells. One of the major toxicities of AZT is depression of the bone marrow and this may be partially overcome with certain protein factors known as colony stimulating factors (CSF). A trial is now underway combining AZT with GM-CSF to study the toxicity and effectiveness of this combination.

In the laboratory, there is a continuing effort to explore new approaches to developing anti-HIV therapies and new compounds. Laboratory studies are being directed at understanding how certain compounds with activity against HIV work. It has been found at the NCI, for example, that a compound called dextran sulphate inhibits HIV infection by interfering with the binding of the virus to cells. This observation has opened the door to explore other agents that may have similar modes of activity. One such agent, known as CD4, will specifically bind to the virus and block its ability to bind to and infect lymphocytes. There is now an early clinical trial ongoing at the NCI to study the effects of CD4 on patients.

Finally, the Program is continuing to explore compounds with novel structures. Recently, a group of compounds referred to as phosphorothioate analogs have been found to be potent inhibitors of HIV infection in cell culture. These are essentially modified small pieces of synthetic DNA that are able to block the production of viral genetic information, resulting in an inability of the virus to produce proteins. Phosphorothioates are now being developed by NCI through preclinical studies with an aim toward their potential use in the therapy of AIDS.

ONCOGENES

Question. Doctor, what new discoveries have occurred in oncogene research?

Answer. Oncogene research has reached a very exciting stage where advances in our understanding of the molecular biology basis for human cancer has advanced to the point where discoveries can now be applied clinically. Molecular techniques for detecting the activation of specific oncogenes are now entering clinical use for the diagnosis of a variety of cancers including lymphomas, leukemias and carcinomas as well as for monitoring the treatment of these tumors. New approaches to treatment are now being developed that specifically interfere with growth factor receptors and their cancer-causing actions at the cell surface. Pharmacologic agents are being developed which can block growth factor receptor

interaction and monoclonal antibodies have also been directed against these cell surface proteins.

At a basic level, oncogene research is leading to a much greater understanding of normal growth control and the molecular switches involved in the processes of normal growth and differentiation. This research is also providing critical new insights into another set of genes, so-called tumor suppressor genes, that normally act to control cell growth and whose loss of function plays an important role in cancer development. When cells lose the functions of these genes, they may then develop into tumor cells. Recently, one such tumor suppressor gene has been isolated from patients with a hereditary form of retinoblastoma, a cancer of the eye. Knowledge of its normal function as well as those of other tumor suppressor genes should provide new opportunities for the early diagnosis of cancer as well as additional insight into how to intervene effectively by interrupting the multi-stage malignant process.

QUESTIONS SUBMITTED BY SENATOR ERNEST F. HOLLINGS

CANCER CENTER CONSTRUCTION

Question. Dr. Broder, in reviewing the fiscal year 1990 budget request for the National Cancer Institute, I was unable to find any monies requested for new cancer center construction. Yet, I have been told repeatedly of the serious deterioration of our research facilities and the inadequate space available to meet our biomedical research needs.

Did your initial budget request to OMB include funds to support extramural funding for facilities and infrastructure?

Answer. In the fiscal year 1990 President's Budget, NCI did not request any funds for construction to support extramural funding for facilities and infrastructure. However, in the fiscal year 1990 By-Pass Budget request, NCI requested $60.8 million to renovate and upgrade facilities on the Bethesda campus and at the Frederick Cancer Research Facility (FCRF) and to support extramural funding for facilities and infrastructure.

Question. What is the historical perspective on construction funds for cancer centers? Specifically, could you please provide me with a chart which illustrates the amounts various cancer centers have received for facilities and infrastructure?

Answer. The following list represents the amount of NCI construction grant monies that have been awarded since 1972 to institutions which are currently designated as cancer centers.

(Dollars in Millions)

Alabama	
University of Alabama Cancer Center (Birmingham)	$4.5
Arizona	
Arizona Cancer Center (UA)	1.7
California	
Kenneth Norris, Jr. Comprehensive Cancer Center (USC)	14.0
Jonsson Cancer Center (UCLA)	8.8
La Jolla Cancer Research Foundation	0.6
University of Southern California Cancer Center	2.3
Armand Hammer Center for Cancer Biology (SALK)	1.8
California Institute of Technology Cancer Center	1.8
Connecticut	
Yale University Cancer Center	7.5
District of Columbia	
Lombardi Cancer Research Center (Georgetown University)	4.0
Howard University Cancer Research Center	5.9
Florida	
Sylvester Comprehensive Cancer Center (UM)	0.6
Illinois	
Illinois Cancer Council	9.4
Indiana	
Purdue University Cancer Center	0.7
Kentucky	
Lucille Markey Cancer Center (UK)	0.2
Maryland	
Johns Hopkins Oncology Center (JHU)	9.2
Massachusetts	
Dana-Farber Cancer Institute	22.5
Worcester Foundation for Experimental Biology	0.4
Michigan	
Meyer L. Prentis Comprehensive Cancer Center (Wayne State)	2.2
Nebraska	
Eppley Institute (UN)	0.4
New Hampshire	
Norris Cotton Cancer Center (Dartmouth College)	0.6
New York	
Cold Spring Harbor Laboratory	1.4
Memorial Sloan-Kettering Cancer Center	10.2
Roswell Park Memorial Institute	6.7
Albert Einstein Cancer Research Center (Yeshiva Univ.)	11.1
Columbia University Cancer Center	6.8
New York University Cancer Center	5.1
University of Rochester Cancer Center	4.8
North Carolina	
Duke Comprehensive Cancer Center (Duke University)	9.8
Lineberger Cancer Research Center (UNC)	1.6
Wake Forest University Cancer Center	0.3
Ohio	
Ohio State University Comprehensive Cancer Center	2.0
Pennsylvania	
University of Pennsylvania Cancer Center	2.5
Wistar Institute	3.0
Rhode Island	
Brown University Cancer Center	0.3
Tennessee	
St. Jude Children's Research Hospital	6.9

Texas	
M.D. Anderson Cancer Center (University of Texas)	8.9
Virginia	
Massey Cancer Center (UV)	0.3
Washington	
Fred Hutchinson Cancer Research Center	11.4
Wisconsin	
University of Wisconsin Clinical Cancer Center (Madison)	7.0
McArdle Laboratory for Cancer Research (Madison)	1.6
TOTAL	$200.8

Question. If Congress is able to provide some funding for cancer construction, please tell me, the Committee, just where these monies would go -- if $5 million, $10 million, or $20 million were provided this account.

Answer. Should additional funds for construction be made available, the predominant share would be awarded to grants applicants through the peer review system. Of significant importance is the maintenance of the Frederick Cancer Research Facility (FCRF). An annual requirement of $2.5 million is required to handle routine repair and improvement needs for this Government Owned Contractor Operated (GOCO) facility, comprised of nearly 70 buildings. Therefore, within the first $5 million increment $2.5 million would be directed to FCRF and $2.5 million to grantee applicants; at the $10 and $20 million level most of the increase would fund grant applications with a portion designated for FCRF needs.

Question. Dr. Broder, I would also appreciate your candid views on the need for facilities money to sustain worthwhile research being performed by cancer centers throughout the country.

Answer. The need for facilities money to sustain worthwhile research being performed by cancer centers throughout the country was well documented in the 1985 "Survey of Cancer Research Facilities Needs" jointly sponsored by Dr. Armand Hammer (Chairman, President's Cancer Panel) and the American Cancer Society. It was concluded that:

- Currently, the majority of cancer research space is reported to be in satisfactory condition: three-quarters of existing space has been built or renovated within the last 16 years. However, almost one-fourth of all existing cancer research space needs substantial work -- alteration, renovation, or total replacement.

- The primary source of construction funds for cancer research is the National Cancer Institute: 44 percent of all requested funding would be to NCI. In other words, to meet 1990 space needs, institutions reported they would request $135.6 million from NCI each year for the next five years. The remaining funds would be sought from other sources, which is consistent with NCI's construction guidelines that require 50/50 matching funds.

- The study's findings indicate crowding in basic research laboratories and a need for additional space in all areas of cancer research -- basic, clinical, animal, and administrative -- by 1990.

The findings about quality of space (its age and its condition) indicate that a significant amount of cancer research space is inadequate.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

IOM REPORT/CANCER CENTERS PROGRAM

Question. I am sure you have reviewed the Institute of Medicine report on the Cancer Center program. Do you agree with the recommendations that the National Cancer Institute "strengthen its core support of cancer centers in order to exploit fully the application of these advances in the prevention and treatment of cancer and its consequences?"

Answer. The Subcommittee on centers from the NCAB has recently recommended criteria for comprehensive cancer centers which, if implemented, will strengthen the cancer centers in a way consistent with the IOM recommendation. Given adequate resources the NCI believes that the centers will be in a strong position with regard to prevention and treatment of cancer. Support for prevention and treatment research come from a variety of funding mechanisms including the Cancer Prevention and Control line item and Clinical Cooperative Groups.

Question. What level of funding for the Cancer Center program was included in your By-Pass budget? How many Centers would that level of funding support?

Answer. NCI requested $136.7 million for 65 cancer centers in the 1990 By-Pass Budget, comprised of $132 million for cancer and $4.7 million for AIDS. The 1990 By-Pass Budget for centers is $35.4 million more than the President's Budget.

Question. Will you take steps to increase the representation of the cancer centers program in NCI planning and decision-making processes?

Answer. The Cancer Centers Program has been represented in the internal planning and decision-making processes of the NCI in a manner similar to other programs within the Institute, that is, through an NCI Division Director's attendance at NCI's executive level meetings. Furthermore, because of the importance of the Cancer Centers Program, cancer centers have historically received the personal attention of NCI directors and their deputies. To facilitate the direct representation of cancer center directors at the NCI, an ad-hoc consultant group of cancer center directors has been selected by the cancer center directors themselves. This group often communicates with NCI.

The NCI is currently assembling an internal committee to develop a five-year plan for the Cancer Centers Program; the staff of the Cancer Centers Program and representatives of other key NCI offices will have key involvement for the development of this plan. External expert advice will be sought; the Centers Subcommittee of the National Cancer Advisory Board will be consulted as well as the ad-hoc group of cancer center directors just described. This

planning process will further define the future goals and structure of the Cancer Centers Program.

ACCESS TO STATE-OF-THE-ART CANCER TREATMENT

Question. In the report of the fiscal year 1989 Labor-HHS Appropriation bill, this Subcommittee expressed its dismay with the limited funding devoted to the Cancer Prevention and Control Program and the limited attention this program enjoys within NCI. I am disturbed that you have actually requested a small decrease in funding in fiscal year 1990 and that your budget justification says, "... studies are being planned to understand the factors the influence physician decision-making, and the incentives and deterrents to practicing state-of-the-art cancer care in a dynamic health service delivery system".

Why has so little progress been made since this Committee discussed this issue last year? Why, after a year, have you only begun to plan studies to improve access to state-of-the-art cancer treatment?

Answer. Funding for the Cancer Prevention and Control program remains constant from 1989 into 1990. This action was mandated as a result of the many competing requirements for research dollars. There are a wide range of programs currently supported by the NCI which are aimed at improving access to state-of-the-art cancer treatment. A large number of these activities are funded through the Cancer Prevention and Control Budget and the Research Management and Support line, e.g., the Physician Data Query (PDQ) computer system, the Cancer Information Service (CIS), a nationwide communications program, and through the Cooperative Clinical Groups mechanism which is responsible for the development and testing of new treatments for cancer. In addition, NCI has begun to require cancer centers to participate in this important activity.

The NCI's Cancer Prevention and Control Program is the principal technology transfer and applications effort within NCI. As part of that Program we are supporting, and have supported for some time, a number of programs and activities directly aimed at increasing the extent to which state-of-the-art cancer treatment and cancer control regimens are applied. These include the Community Clinical Oncology Program (CCOP) designed to bring the benefits of the most up-to-date cancer treatment and control research to patients in their own communities, the newly proposed minority-based CCOP, and the Public Health Initiatives which are increasing the number of states involved in broad-scale cancer control planning.

At the same time these programs are continuing we are continuously evaluating their effectiveness in meeting the goal of improving access to state-of-the-art cancer treatment. The studies we are planning will enable us to have a more fundamental understanding of the process by which physicians seek out and adopt state-of-the-art regimens. This information will be used to improve the programs we are currently funding and to design new ones.

PATIENT CARE COSTS FOR CLINICAL TRIALS

Question. According to recent reports by the Institute of Medicine and others, there has been increasing reluctance on the

part of third-party payers to cover patient care costs for individuals enrolled in clinical protocols. To what extent are such payment practices by either private insurance companies or the Medicare program having a negative impact on your ability to carry out research protocols?

Answer. The practice by third party payers including Medicare to deny coverage for the patient care costs of investigational therapy is hampering patient accrual to Phase I studies which often require that patients be hospitalized to receive treatment. Patients are hospitalized so that they can be closely observed for toxicity as Phase I studies represent the first time that new agents are administered to human beings. Several of the NCI Phase I clinical investigators have reported difficulties in obtaining reimbursement from Medicare and other insurers for Phase I trials. This has resulted in slowed accrual to several Phase I trials. Many insurance companies require "precertification" for a hospital admission in order to screen for medically-unnecessary admissions. Increasingly, precertification is being denied for admission to receive an investigational agent both in Phase I and Phase II studies. NCI is particularly aware of this trend in the LAK/IL2 immunotherapy trials that are being conducted by NCI-designated cancer centers. Patient accrual to these studies is being hampered by third-party reimbursement policies which deny payment for LAK/IL2. This practice also has the consequence of making this therapy inaccessible to many patients. For both LAK/IL2 and other Phase I and Phase II agents that require hospitalization, if a patient's insurance company will not provide coverage, the patient most often does not receive the investigational therapy unless he or she can afford to pay.

Little data exist on the precise consequences to clinical trials accrual of the third-party payors reimbursement policies. NCI has received many anecdotal letters from physicians treating patients on outpatient clinical trials who have also been denied reimbursement. Patients and physicians are being denied reimbursement for treatment with investigational agents in the outpatient setting as well as the inpatient setting but data describing the extent of this problem have not been compiled. The American Society of Clinical Oncology (ASCO) and the National Coalition for Cancer Research (NCCR) are working with NCI to survey the oncology community in an attempt to determine the magnitude of this problem.

Question. What about the impact on the ability of patients with diseases like cancer or AIDS to receive the best quality health care?

Answer. The growing practice of third-party insurers to deny payment for investigational therapy has two primary consequences: 1) the pace of clinical research is slowed and 2) investigational therapy increasingly becomes the privilege of patients who can afford to pay for this treatment. It is an unfortunate reality that many hospitals cannot afford to admit a patient for investigational therapy knowing that a patient's insurance company will not provide reimbursement for the costs of treatment. Therefore, increasingly, patients are having to pay for therapies such as LAK/IL2, bone marrow transplantation and Phase I or II studies which require hospitalization. Since few patients can afford this level of

expense, these potentially life-saving or life-prolonging therapies are becoming accessible only to the financially privileged.

Question. Isn't it true that treatment given to cancer or AIDS patients under a clinical protocol often represents the best available care, or even the only hope for the patients' improvement?

Answer. Yes, NCI strongly supports the idea that treatment with investigational therapy on scientifically meritorious clinical trials is standard therapy for cancer patients for whom no reliably curative therapy exists. NCI and other nationally-approved clinical trials are designed to offer patients therapy that is at least equivalent to and the hope is, better than, the "standard" therapy available to patients outside of a clinical trial. Patients must be offered investigational therapy that is at least as likely to be effective as "standard" therapy in order for the clinical trial to pass the ethical and scientific peer-review process. Because no reliably curative therapy exists for many cancer patients, NCI believes that participation in a clinical protocol represents a patient's best chance for cure or for a meaningful therapeutic response.

Question. I understand that many in the oncology community are also concerned about payment practices with respect to chemotherapy, and more specifically the denial of coverage for conditions other than those mentioned on the FDA-approved label. Is the refusal to pay for unlabeled indications also a threat to your ability either to carry out important research or to provide the best available patient care?

Answer. Yes, the history of cancer drug development in our country shows that the most beneficial uses for new agents are generally discovered in the post-marketing phase, that is, after a drug has been approved by the FDA for marketing of the labelled indication. This is most likely because new agents become widely available for testing in various cancers after they are FDA-approved and on the market. This tendency of third-party payers to reimburse only for the indication cited on the FDA label threatens the drug development and clinical testing that occurs in the post-marketing period. In addition, patients are denied access to effective therapies if only the labeled indication is reimbursed. For example, alpha interferon, until recently, was approved only for use in the rare cancer, hairy cell leukemia. However, this agent is also effective in treating lymphomas, chronic myelogenous leukemia, multiple myeloma, kidney, ovarian cancer and others. Patients are increasingly being denied payment for alpha interferon for use in cancers other than hairy cell leukemia. This is unfortunate because the FDA never intended that their labelling indications would be used as a guidelines for reimbursement. FDA does not attempt to list all the potentially efficacious uses for a new agent on the label, but rather lists only the indication that the sponsor applied for in the New Drug Application (NDA). Third-party payers are relying on the FDA label to provide information that it was not intended to provide, that is, the list of medically acceptable uses for an approved agent. NCI believes that, at a minimum, the three compendia named in the Medicare Catastrophic legislation should be used to determine which "off-label" indications for FDA-approved anti-cancer agents are considered medically acceptable and therefore subject to reimbursement.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

FUNDING FOR CANCER CENTERS

Question. Dr. Broder, as you know, there are as many as five NIH funded cancer centers located in Pennsylvania. As a result, not only do Pennsylvania scientists rely on these centers to conduct state-of-the-art cancer research, but many residents of Pennsylvania are dependent on the research at these centers for new cancer treatment and therapies.

What is the fiscal year 1990 budget request for all of the NIH cancer centers?

Answer. The fiscal year 1990 request for cancer centers is $101.3 million, which is comprised of $96.6 million for non-AIDS activities and $4.7 million for AIDS-related activities.

Question. How does that compare to fiscal year 1989?

Answer. In fiscal year 1989, the NCI appropriation for cancer centers was $101.3 million, including the funding for AIDS related activities. The total fiscal year 1990 request is the same amount as the fiscal year 1989 appropriation.

Question. How much would the NCI need in fiscal year 1990 to maintain current services for the centers program?

Answer. If the fiscal year 1990 current services is assumed to be the same number of current centers, i.e. 60, with a 3.6 percent inflationary increase, then the total amount to maintain current services is $111 million.

Question. How much would you need to fund all of the centers at their fully approved level?

Answer. To fully fund the 60 research centers in fiscal year 1990 at their peer reviewed recommended levels would require an additional $21 million, for a total of $121.3 million.

Question. What is your response to the recommendation in the Institute report that calls for you to take immediate steps to avert a crisis in the funding of the program during fiscal year 1989 and to develop an adequate budget for fiscal year 1990?

Answer. Within the present economic circumstances, the only response that I can make to the IOM's call for immediate steps to avert a "crisis" is to say that NCI's priorities are such that cancer centers must undergo some changes, and possible funding restructuring, in order to maintain their designation as NCI centers and to also retain their funding status.

FUNDING COOPERATIVE CLINICAL TRIALS

Question. Dr. Broder, what is the fiscal year 1990 budget request for the Cooperative Clinical Trials Program?

Answer. The amount in the 1990 budget for the clinical cooperative groups is $59.5 million. These awards provide the primary means of support for NCI's extramural treatment clinical trials research, a program of critical importance as it is one of the final links between cancer laboratory research and accepted state-of-the-art treatment.

Question. In your professional judgment, is the NCI capable of spending more than the budget request for this program?

Answer. Yes, to fully exploit the potential of the groups' clinical trials program, additional funds could be utilized by this program.

Question. If so, how much more and how would the funds be spent?

Answer. In the By-Pass Budget for 1990, the professional judgement budget of the Institute, $78.9 million was requested for the clinical cooperative groups. Major initiatives which could be exploited at this level include the start-up of trials to explore the use of adjuvant therapy in solid tumors, including those of the breast, colon and rectum.

Also of prime importance would be an increase of patient accrual rates into all national high-priority trials. By increasing the numbers of patients in a trial, we are able to accumulate data at a more optimal rate, thus reducing the time necessary to draw statistically valid conclusions about the particular treatment protocol being tested. Included in patient accrual efforts would be efforts to increase minority representation in group-sponsored clinical trials, as well as enroll greater numbers of patients over age 65.

QUESTIONS SUBMITTED BY SENATOR JAMES A. McCLURE

NEW APPROACHES IN TREATMENT RESEARCH/RADIATION THERAPY

Question. Most cancer patient cures are a result of radiation therapy. The available x-ray facilities have limited capability for dose localization. There are several radiation modalities (such as proton, heavy-ion, and neutron capture therapy) that offer dramatic dose selectivity and, therefore, the opportunity for increased treatment effectiveness.

The NCI cancer treatment research and development focus is almost entirely on medical oncology or immunology with little attention to advanced radiation technologies in the requested budget.

What is the basis for NIH/NCI inattention to these promising approaches to cancer treatment? What will be done to improve the situation?

Answer. It is incorrect to say that most cancer patient cures are a result of radiation therapy. While many early stage cancers may be removed or placed into remission by local treatment modalities, such as surgery or radiation therapy, there is ever

increasing information to suggest that systemic adjuvant therapy (i.e., chemotherapy, hormonal therapy or immunotherapy administered after local disease has been eradicated through surgery or radiotherapy) increases the disease-free survival and possibly overall survival in breast, colon, rectum and lung cancers. Therefore, cancer treatment is more of a multi-modality approach today than it has ever been in the past.

Photon beam, i.e. x-ray, therapy has been the mainstay of radiotherapy for 70 years. The efficacy as well as limitations are more precisely worked out for this form of radiotherapy than for any other form. There are, however, several promising new areas of radiation therapy research under development which may prove to be more effective in delivering the radiation to a higher dose in a more carefully controlled way. Research in the field of radiation therapy is conducted through the Institute's Radiation Research Program (RRP). Ongoing basic and clinical research projects under the auspices of RRP include research with fast neutron beam therapy, boron neutron capture therapy (BNCT), hyperthermia, the development of radiation sensitizers as well as radiation protectors, proton beam therapy, and heavy ion therapy. While there are many promising leads in each of these programs, there are several obstacles which have hampered more rapid development of these treatment modalities. First of all, the technology behind each of these radiation delivery systems is quite complex and, this has limited the number of facilities available to treat patients, as well as the number of patients who could be treated at any of the facilities. Second, patient accrual onto these clinical trials has been slower than planned. This problem is due to several factors including the locations of the few facilities that are available, the rarity of the tumors most sensitive to these approaches, and lack of physician awareness or willingness to refer patients to these radiation therapy clinical trials. Actions are being taken to improve patient accrual through a concerted effort of the NCI, the American Cancer Society and the American College of Surgeons to increase physician awareness of clinical trials and to encourage referral of patients onto these trials. The technical difficulties associated with these modalities will require time, money and technological advancement in these areas for this problem to be overcome.

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

STATEMENT OF DR. ANTHONY S. FAUCI, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next we will go to the National Institute of Allergy and Infectious Diseases, and Dr. Fauci.

We're back again to AIDS, Dr. Fauci. We have not exhausted that one yet.

Dr. FAUCI. Mr. Chairman, Senator Bumpers, the National Institute of Allergy and Infectious Diseases is devoted to fundamental and clinical research on the immune system and its disorders, as well as the prevention and treatment of the whole host of infectious diseases that afflict mankind.

As I have said to this committee on other occasions, and just a few moment ago, in my response to Senator Bumpers' question, it is critical to continue to support the basic research on the immune system, microbiology, and infectious diseases, for certain it will not only have immediate impact on the science base, but it will have important extrapolations in the future.

Let me give you just one or two examples of how, over the past year, undifferentiated fundamental research has led to potential important discoveries that have wide-ranging implications.

Investigators funded by NIAID have come up with a mouse model of the human immune system, called the Severe Combined Immuno-Deficient, or SCID mouse model, in which a mouse is born congenitally without an immune system. Investigators have been able to transplant a normal human immune system into the mouse, whereby you now have a mouse who has a normal human immune system.

The experiments that have been able to be done on this mouse regarding transplantation, vaccination, infectious disease research, and, most recently, to infect the mouse by the AIDS virus, the Human Immuno-Deficiency Virus, since that mouse now has a susceptible immune system, will have far-reaching implications.

In addition, we spoke last year about the structural biology program, whereby one uses x-ray crystallographic techniques to define the fine structure of various microorganisms. This has been done some years ago, with the virus Rhinovirus, which is the virus associated with the common cold. As a result, molecules that are essentially the receptor for the virus on nasal cells have been identified; leading to the possibility for the first time to actually do something about the symptoms and the cause of the common cold.

Moving on to AIDS, as we alluded to just a moment ago, AIDS assumes approximately 50 percent of the NIAID budget. We have a number of activities in basic and clinical research, just to briefly

summarize in the area of clinical trials, an awful lot has happened in the past year.

In our clinical trials program, there are now approximately 7,000 individuals on clinical trial. There are 27 drugs being tried, and there are 54 active protocols.

We have placed an emphasis over the past year on minority participation in clinical trials, as well as minority staffers in the science of clinical trials, and we have established a community program for clinical research on AIDS whereby we might have wider access of community physicians, as well as community constituents in our clinical trial program.

PREPARED STATEMENT

In summary, Mr. Chairman, we have focused on basic biomedical research. We feel that it is extremely important, not only now, for the science base, but also for the extrapolation into clinically important activities in the years to come.

I would be happy to answer any questions you might have.

[The statement follows:]

STATEMENT OF DR. ANTHONY S. FAUCI

As we enter the final decade of this century, it is time to reflect upon the mandate, direction, and goals of the National Institute of Allergy and Infectious Diseases (NIAID). Over the past year, we have evaluated our approaches to the medical challenges we face and sought comments from our scientific constituents regarding proper directions for the Institute.

The theme that is continually reiterated is the importance of our fundamental commitment to the basic science foundations of the Institute. This commitment has been key in our development, has placed NIAID in the forefront of many of the extraordinary advances that have occurred in biomedical research, and is the beacon for where we are headed. Our reliance on and dedication to sound scientific principles have enabled us to make major contributions in several areas.

One of these areas is AIDS. Although the magnitude and severity of the AIDS epidemic are still being realized, we can now offer a message of hope to the thousands of HIV-infected persons and their loved ones. While we do not have a cure for AIDS, and much work lies ahead, patients are living longer and better. Real progress has been achieved in a relatively short time due to the basic science research foundation I have just mentioned.

Using basic research techniques, scientists have delineated the functions of virtually all genes of the AIDS virus. We know how some viral genes interact with genes of human cells. These facts are helping us to unravel the complex process that determines how well HIV replicates in cells and to understand the apparent inactivity of HIV in some infected cells.

Knowing the chemical structure of HIV genetic material has enabled scientists to use a new research technique called polymerase chain reaction, or PCR, with important clinical results. PCR can multiply minute quantities of genetic material in a blood sample, thus enabling detection of viruses that may be hidden in one in a million white blood cells. PCR may be useful for early detection of HIV infection enabling earlier treatment interventions, measurement of HIV reduction in patients being treated with antiretroviral agents, and diagnosing HIV infection in newborn babies.

Developing safe and effective anti-HIV agents is one of NIAID's top priorities. The Institute has established 28 National Cooperative Drug Discovery Groups, comprising teams of experts from industry, academia, and government. The groups screen existing compounds and, using knowledge gained from basic viral research, design potential anti-retroviral agents.

Already several experimental drugs have emerged from their work, an unprecedented accomplishment. One of these, called recombinant soluble CD4, is being tested in phase I clinical trials, and the story of its development illustrates the vital relationship of basic and clinical research.

Basic research scientists identified CD4 as a protein on the surface of the human T4 cell and other cells to which HIV attaches. After attachment, HIV can invade, and thus infect, the cell. This led to cloning the CD4 molecule and use of the cloned substance as a decoy. Scientists hope that HIV will be fooled into attaching itself to this free-floating or soluble CD4 rather than to healthy cells. A promising variation of soluble CD4 therapy was developed by NIAID and National Cancer Institute scientists. They linked the CD4 with a poison produced by soil bacteria to produce a "guided missile" that seeks out and kills HIV-infected cells.

While targeted drug development is essential, carefully designed and executed clinical trials are the only way to determine definitively which drug is effective and safe. Our extramural clinical trials effort includes a nationwide network of 45 AIDS Clinical Trials Units, including 13 pediatric Units. This year we are initiating the Community Programs for Clinical Research on AIDS to include community physicians and their patients in clinical trials. Their commitment and experience will enhance the design and implementation of AIDS-related research projects, which will be responsive to community needs as well as scientifically sound.

NIAID is also conducting clinical trials of AIDS vaccines. Two are being studied, and we expect that other candidate vaccines, as they become available, will be evaluated in phase I trials.

Complicating the development of an AIDS vaccine, and of AIDS drugs as well, has been the lack of an adequate animal model in which to test candidate products. During the past year, NIH scientists developed two models of HIV infection in animals.

The first is a transgenic mouse that contains complete copies of HIV genes in every cell of its body. NIH scientists first injected HIV genetic material into fertilized mouse eggs that were then implanted into adult female mice. When born, the young mice had no sign of disease, but some of their offspring developed AIDS-like symptoms.

A second animal model, developed by two NIAID-funded research teams, opens the door to studies on an extraordinary variety of infectious diseases and human immune disorders. Both teams used specially bred mice with a genetic disorder known as severe combined immune deficiency (SCID) syndrome. By transplanting or injecting human immune cells into these mice, the investigators developed colonies of experimental mice that can be used to study the most fundamental characteristics of the human immune system.

Here again, we have an example of how our commitment to basic research can contribute to clinical advances. By using this model to better understand the basic mechanisms of immune system function, we can develop ways to restore damaged immune function, suppress the immune system when it reacts inappropriately, and enhance defenses against infectious agents. The SCID mouse model will also help investigators in their struggle to improve the body's acceptance of transplanted tissue.

An important practical application of immunologic research is vaccine development, a keystone of NIAID's research program. New techniques have opened the way for producing highly purified and

specific proteins that can be incorporated into vaccines for old and newly recognized diseases. These diseases include pertussis and Lyme borreliosis, the most common arthropod-borne disease in the United States.

However, the new tools of science require well-trained individuals to use them. I have been concerned for many years that the erosion of the base of research investigators will ultimately cripple our ability to achieve the kinds of results I have been describing. We must renew our commitment, not only to the concept of basic biomedical research, but also to training people to do this research.

AIDS has shown us how devastating infectious diseases can still be. It has also shown us the importance of continuing the basic research to delineate the regulatory mechanisms of the immune system. I believe we have the tools to conquer AIDS, and we have the commitment to basic science that will enable us to meet future challenges as well.

Mr. Chairman, the FY 1990 budget request for this Institute is $442,596,000. I will be pleased to answer any questions you may have.

AIDS BUDGET

Senator HARKIN. Dr. Fauci, let's just jump right into the AIDS battle.

Fifty percent of your budget goes to AIDS. It is projected to grow by 24 percent, is it?

Dr. FAUCI. It is projected to grow by 28 percent.

Senator HARKIN. By 28 percent in 1990.

Is it as big as the cancer budget now?

Dr. FAUCI. No.

Senator HARKIN. AIDS, in total, I mean.

Dr. FAUCI. The AIDS budget in total for the NIH is $752 million, which is not as big as the total cancer budget.

Senator HARKIN. HHS totals how much?

It's $1.6 billion, I am told. But for you, in your shop, it is what?

Dr. FAUCI. In NIAID, it is $400 million, which is approximately 50 percent of the total Institute's appropriation.

Senator HARKIN. How do you correlate with all these other ones, the CDC, ADAMHA, and all the others? All the other ones add up to $1.6 billion.

Dr. FAUCI. OK.

Senator HARKIN. This is all research on AIDS. Who coordinates it?

Dr. FAUCI. The NIH clearly is the lead agency. We have 47 percent of the AIDS money. The FDA has 3 percent; the CDC 30 percent; ADAMHA 13 percent; and so on.

Senator HARKIN. Then CDC is right behind you.

Dr. FAUCI. CDC is 30 percent, yes; right behind us.

Senator HARKIN. How do you work with them. Tell me how you do that. Do you do that, do you work with them closely?

Dr. FAUCI. Very closely, Mr. Chairman.

Senator HARKIN. Are they under you?

Dr. FAUCI. No; they are not.

All the agencies report to the Assistant Secretary for Health. We, Dr. Wyngaarden and I, are on the Public Health Service AIDS Executive Committee, in which we represent the NIH. Representatives from the CDC are also on the Public Health Service AIDS Executive Committee.

Senator HARKIN. Do you and Dr. Wyngaarden both feel that this relationship between you and the CDC is working to get a good cross-fertilization?

Do you know what is going on?

Dr. FAUCI. Yes.

Dr. WYNGAARDEN. Yes; we meet every other Monday for 1½ hours or so, and, of course, there is a lot of informal interaction in addition to that.

AIDS BUDGET COMPARED TO NON-AIDS

Senator HARKIN. Your institute shows less than a 3 percent growth for non-AIDS activities, and a 28 percent growth for AIDS.

Dr. FAUCI. Yes, sir; it's 2.7 percent in non-AIDS.

Senator HARKIN. Let me ask you this question.

What if we leveled AIDS off to a 20 percent growth in 1990, and invested the money saved in other biomedical research. Would this be a significant setback for AIDS research or not? I'm talking about 20 percent, rather than 28 percent.

How much is that in dollars?

It saves about $75 million.

Dr. FAUCI. I think this would fall under the category of robbing Peter to pay Paul, Senator. So it would be a very difficult question to answer.

I answered the question a while ago of Senator Bumpers and yourself regarding the amount of money that Dr. Wyngaarden and I asked for, for the NIH as a whole, as well as for the individual institutes, and the amount of money that we feel can be effectively spent in AIDS research is a greater figure than what we are getting.

Although that 28 percent, comparatively speaking, is greater by far than the 2.7 percent in non-AIDS, we feel that the money in AIDS is money that is needed.

On the other hand, we feel strongly that the 2.7 percent increase in non-AIDS is not commensurate with the scientific opportunities.

NON-AIDS BUDGET INCREASE

Senator HARKIN. So you say the 2.7 percent increase for non-AIDS activities is not—there is a lot out there, isn't there, like Lyme disease.

Dr. FAUCI. Yes, sir; that's part of the activities of the Institute, together with the Arthritis Institute.

Senator HARKIN. Has that not been increasing, Lyme disease?

Dr. FAUCI. The answer is yes. What we are talking about is not necessarily that something is being cut, but that non-AIDS is not

growing at a rate that we feel the scientific opportunities would allow.

That is one of the big problems. When people talk, as I think in that letter, that non-AIDS is getting cut, it isn't getting cut; but it isn't growing as fast as it should. There are entire areas of NIAID that we feel are not growing as fast as they could.

Senator HARKIN. Dr. Fauci, if it's not even keeping up with inflation growth, then it is a cut.

Dr. FAUCI. Indeed. It is not a good situation.

Senator HARKIN. And 2.7 percent does not keep up with inflation's growth.

Dr. FAUCI. Right.

Senator HARKIN. So, it has to be a cut.

Dr. FAUCI. Don't get me wrong. It's not good.

AIDS CASES

Senator HARKIN. I understand. I don't want to put you between a rock and a hard place, but we have to make some choices here. We are going to try to get all the money that we can for this budget. I know what Senator Bumpers' interests are, and this subcommittee's. We don't know what our allocation is going to be for the Budget Committee. But I am just laying the groundwork for making some hard choices down the line.

We have had this huge increase in AIDS research. You say that you could use more. You could use more all across the board.

Again, the information that is coming in to me about AIDS, in terms of basically the number of AIDS cases, is that they are not increasing that rapidly, that it's being focused in a certain segment of our society, that it is not spreading, that we have a big hump coming of people who are HIV infected now who will develop AIDS. That is coming in the next few years. Obviously, that is what a lot of your research is directed toward.

Dr. FAUCI. Right.

Senator HARKIN. But in terms of new incidents, new cases of HIV infected people, again, correct me if I am wrong, but I understand that is going down.

Dr. FAUCI. That is not the case, Senator.

Senator HARKIN. Or leveling off?

Dr. FAUCI. Well, we are not sure because we do not yet have the framework in place where we can have a broad, homogeneous screening of the population and knowing what is the case.

Let me just make a minor correction in something you said.

This is often confused. To say that the number of AIDS cases is slowing down or leveling off is not correct. The projections from the CDC are that we will have a cumulative number of 365,000 cases by 1992. If you look at the mathematical models that have been created projecting about 90,000 cumulative cases now, we are right on the mark. Based on these models we can project that we are going to have a lot more AIDS cases.

But if you talk about new infections, you have to break it down according to what particular risk category group you are talking about.

A typical example is this. If you looked in San Francisco in 1982, the number of new cases among gay men in San Francisco was 19 percent per year. Now it is less than 1 percent per year.

What we are seeing now is a relatively proportional increase among inner city areas of IV drug abusers, their sexual partners, and the children born of either IV drug abusers or the sexual partners.

The unknown is the areas in the country on which we do not have a good epidemiological handle. But to say that it is going down, new infections, in some groups, and going up in others, is correct, as I have just outlined for you.

Senator BUMPERS. If I may——

Senator HARKIN. Surely.

NEW INFECTIONS WITH AIDS

Senator BUMPERS. My daughter worked in an AIDS clinic as a volunteer, in San Francisco. I just came back from there Saturday. She gave me the same information you just gave me. But I want to be sure that I understand it.

For example, in San Francisco, the number of new infections is up 1 percent.

Dr. FAUCI. The number of new infections, right.

Senator BUMPERS. Now, the number of infected people was always high and the number of cases that manifest themselves is going up.

Dr. FAUCI. Absolutely correct.

Senator BUMPERS. Now, that is due, I take it, that small increase in the number of infections, is due to an educational program.

Dr. FAUCI. It is a combination of an educational program as well as something of a saturational effect. You are dealing with a city in which a very high percentage of the gay men in that city are already infected. So there is some saturational effect.

That is not to downplay the fact that there has been extraordinary modification of behavior and the kind of extremely high risk behavior that occurred prior to the realization that this was a transmissible disease for the most part has now gone down dramatically in that population.

Senator BUMPERS. Now you don't have comparable data in much of the country as you have in San Francisco, is that true?

Dr. FAUCI. That's correct.

Senator BUMPERS. Thank you, Mr. Chairman.

Senator HARKIN. Thank you, Senator Bumpers.

CLINICAL TRIALS UNABLE TO FUND

Dr. Fauci, I have a list of eight clinical trials, several for the development of childhood vaccines, which I know Senator Bumpers is extremely interested in, that you could start in 1990 if funds were made available.

These include childhood asthma, pertussis vaccines, an Influenza A vaccine——

Dr. FAUCI. Right, and rotavirus.

Senator HARKIN. Yes.

Dr. FAUCI. Haemophilous Influenza B, neonatal herpes, genital herpes.

Senator HARKIN. You know then all, right.

Well, here we go: First year costs of $9.4 million; total projected costs $30.3 million.

Most of these are for what, childhood?

Dr. FAUCI. Many of them are.

Senator HARKIN. Many of them are for childhood.

Dr. FAUCI. Many of them are vaccine related trials that are childhood related.

Senator HARKIN. Tell me about the importance of that.

Dr. FAUCI. It is quite important, Senator.

I could take one or two as an example.

Senator BUMPERS. Take Haemophilous Influenza.

Dr. FAUCI. Haemophilous Influenza B is an extremely important disease. It is a cause of serious central nervous system infection and meningitis in children and infants.

It is important because it's one of the leading causes of mental retardation and deafness in children.

The difficulty is that the vaccine that is available is effective in children who are older than 18 months of age. And yet, the infection itself is most devastating and common in infants who are less than 18 months of age.

What we really need to do is to get a trial with the right product to be able to induce an effective immune response in those children from birth to 18 months old. That is a very important clinical trial.

This is a very devastating disease in infants.

Senator HARKIN. Well, you don't have any money available for any of these starts, right?

Dr. FAUCI. No; those are eight that we cannot fund at all.

Senator HARKIN. Senator Bumpers assures me that you will find the money.

Senator Bumpers, do you have any questions?

CONSOLIDATION OF AIDS FUNDING

Senator BUMPERS. I just have one. I wanted to get into that, and I think you have already asked all I would get into on that.

One question, Dr. Fauci.

As I look over the distribution of AIDS funding, for example, NCI gets $151 million; heart, lung, and blood gets $42 million, we dole this money out to these various Institutes here, we make those decisions.

Dr. FAUCI. Right.

Senator BUMPERS. The administration has always wanted to put AIDS funds into a consolidated account. Congress has always resisted that, and I don't mind telling you that I am not about to appropriate $750 million to some assistant secretary who got his job because he raised a lot of money and then let him dole it out to these various Institutes.

The only other alternative to this might be this. You know, we are not uniquely qualified to make these decisions, either. The only other thing that I might suggest would be that we, for example, make a block grant to NIH if you had some system established

there whereby you would then parcel the money out to these various Institutes in something like this, or some different priority.

What is your feeling about this?

Dr. FAUCI. Well, Senator, my feeling has always been that funds should be appropriated as directly as possible to the unit that is responsible for the research involved.

To add another layer, another step, in the process of the appropriation itself I believe may slow things down in being able to move quickly.

That is not to say, as has been discussed by Dr. Wyngaarden in the past, that there should not be some set-aside funds in addition to the appropriations directly to the Institutes that the Director of NIH could use to move around on opportunities as they arise. That is different, I believe, than taking the whole bundle of it and just putting it in one place.

So, as a scientist and as a science administrator, my preference would be for the funds to go directly to the Institutes.

DISCRETIONARY FUNDS

Dr. WYNGAARDEN. Senator Bumpers, I would like to support that position, and also the idea of a Director's discretionary fund. I have not had a nickel in a now $7 billion budget.

Senator BUMPERS. You are talking about AIDS discretionary money?

Dr. WYNGAARDEN. AIDS and everything else.

Senator BUMPERS. You don't have any discretionary money?

Dr. WYNGAARDEN. No, Senator; I do not.

Senator BUMPERS. I understood at the beginning of this thing that you did have discretionary funds.

Dr. WYNGAARDEN. No, I have never had discretionary funds, except for one $10 million appropriation for structural biology of the AIDS virus, and that has now been committed.

This budget, for the first-time, requested $25 million of discretionary funds for the Director. Of course, the Assistant Secretary, now departed, has already obligated $20 million of that. The principle, however, is correct.

Senator BUMPERS. I can see why you are leaving, Dr. Wyngaarden. [General laughter.]

Dr. WYNGAARDEN. I'm free to say a few things that I might not otherwise say.

Senator BUMPERS. Very liberating, isn't it? [General laughter.]

Senator HARKIN. Let me ask about that. I didn't ask about that $25 million earlier.

If you got $25 million in discretionary money out of—of what?

Dr. WYNGAARDEN. Out of a $7.2 billion budget.

Senator HARKIN. Yes; out of $7.2 billion—what does that mean?

Dr. WYNGAARDEN. Well, it's a step in the right direction.

Senator BUMPERS. It means there are things that come up out there that nobody could foresee and he is powerless to do anything about it. That is what discretionary money is for.

Dr. WYNGAARDEN. Exactly.

For example, we talked about the training situation that we are in. If I had the $25 million in the 1989 budget, we would have han-

dled that training issue. It would have been a top priority for some discretionary funds. We would not have had to rebudget. We would not have had all these complaints from the extramural community about the financial straits that this has created.

Senator HARKIN. I was going to ask about that. I just thought that $25 million did not seem like very much. We know what the training grants and the stipends are. Why don't we just put it in that budget?

I have an open mind on the discretionary funds. I would just like to know more about how you would address problems with it.

[The information follows:]

DIRECTOR'S DISCRETIONARY FUND

This proposed $25 million fund would be set up within the Office of the Director to allow NIH to be more responsive to emerging research opportunities and health priorities. It would enable NIH to respond rapidly to unanticipated needs without requiring a redirection of funds from other important activities. Amounts will be allocated to NIH components and funding mechanisms as the needs become apparent. Had this type of fund been available in fiscal year 1989, it could have provided support for the stipend increase in the research training program without causing such a large reduction in the number of trainees to receive support. Another example of a use for this fund would be to provide matching funds to the BID's to support the new effort to encourage minority participation in biomedical research through the supplementation of research project grants. As yet another example, had we had such a fund in 1982 and 1983, the AIDS effort would have been launched more expeditiously without detracting from other program needs.

SALARY ISSUES

Senator BUMPERS. Mr. Chairman, one other question I never really did nail down with Dr. Wyngaarden is this.

This figure of $99,000 for senior researchers, what should that figure be? I mean, if Congress is going to decide to raise the salaries of judges, which it is not likely to do, but if it does, we ought to get into this executive salary, too.

What should the figure be?

Dr. WYNGAARDEN. We have a proposal that was introduced some years ago, and it is modified annually, for a Senior Biomedical Research Service. The current proposal in the Department is to index that, to have it market based.

A specific proposal would call for a base salary plus two potential additions, one for scientific accomplishments and responsibilities and another for administrative competence and responsibilities.

This would be indexed, then, to the AAMC figures—not 100 percent of the average, but some fraction: 80 percent in one case and 70 percent in another.

I think 20 percent of the group would be eligible for the higher level. The last figure that I saw there for the highest possible level would be about $154,000. Below that, the cap would be something around $140,000, perhaps, and then shaded down from there.

It would be subject to adjustments periodically, based on the AAMC figures. This would allow us to maintain a much more competitive posture.

Senator BUMPERS. Dr. Wyngaarden, you stated a moment ago that you have been able to recruit within the Government some fine senior scientists. But as these people leave in increasing numbers, you do lose a lot of continuity, don't you, and experience?

Dr. WYNGAARDEN. We do, indeed. We can give you many examples of people we would have loved to hold for another 10 or 20 years, if it were possible. We lose these people when they begin to face steep educational costs for their children.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator BUMPERS. So that's when you lose them, as their children reach college age?

Dr. WYNGAARDEN. Yes.

Senator BUMPERS. Thank you.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

FUNDING FOR AIDS RESEARCH

Question. Dr. Fauci, your name perhaps more than any other is associated with AIDS research. You have seen it grow dramatically since FY 1982. Total AIDS funding is projected to grow by 24 percent in FY 1990 to $1.6 billion, almost as big as the cancer budget. Cancer has six times the mortality rate as AIDS but now the funding is almost the same. When is enough enough?

Answer. There are two aspects to that question. For many years the U.S. has held the leadership position throughout the world in biomedical research. This success is only possible because of an important and key role that the Congress plays in the appropriation process. The balance which is drawn by both the Administration and the Congress between competing priorities throughout the government and still holds biomedical research as an important priority allows researchers throughout the country to continue to capitalize on the available technology. Thus, to answer whether sufficient funds exist would be to respond to whether there are sufficient technological advances to still warrant considerable resources in the area of research, particularly AIDS. As was the case in the 1970's with the National Cancer Institute buildup, much of the support for basic research, which may be targeted to a specific research area, such as AIDS, will pay dividends in areas other than that specifically intended at the time. A notable example is the basic support for virology research that occurred during the 1970's, and played a key support role in helping to identify the virus which causes the HIV infection. As we have often stated, there are still a great many research questions which need to be answered and which will play an important role in helping to identify better therapies and vaccines for AIDS and whose benefit to areas other than AIDS research will be clearly documented.

The second aspect of this question is whether we are concerned that the support for non-AIDS activities has been diminished as a result of our responsibility in AIDS research. To this question I have expressed my concern that as we have played a leadership position in the research and fight against this important public health priority, we should not have our non-AIDS activities compromised. The research other than AIDS in areas of vaccine development, infectious diseases, basic immunology, and others are important not only to our own Institute but to most of the Institutes at the NIH. The NIAID's leadership position in basic immunologic research has formed a foundation of research which helps support the advances in many of the other Institutes. I would suggest that the support for these important areas should continue at a pace at least equal to those of other Institutes.

In summary, there are a great many research activities which exist both in AIDS and in other than AIDS research. We feel that each of these are important enough to warrant continued support by the Congress and the Administration. We also feel that neither should be supported at the expense of each other.

COMMUNITY BASED CLINICAL TRIAL PROGRAM

Question. Last November after the appropriations bill was passed the Allergy Institute started a new program or mechanism

called the community based clinical trial program, permitting community physicians--away from the big research hospitals--to administer and monitor AIDS patients receiving experimental drugs. Tell the Committee the advantages of this program, and have you been satisfied with the level of the science conducted by this community trial program?

Answer. The Community Programs for Clinical Research on AIDS (CPCRA) of NIAID's AIDS program was established to take advantage of a unique opportunity which exists today. Many thousands of persons at risk for HIV infection have heeded the advice of their primary care providers as well as the recommendations of the Public Health Service and have been tested for the presence of antibodies to HIV. The vast majority of these persons who are infected with HIV are cared for in their home communities by their family doctors and community clinics. Many of these persons, their family members and their family doctors are willing, in fact desperate, for access to clinical research on various aspects of HIV disease. They may lack access to available clinical research due to geographic limitations or inability to meet entry criteria of clinical trials sponsored at universities or medical centers which are conducting HIV-related research. Thus there is a great advantage to bringing research opportunities to the clinicians who provide care to persons with HIV infection. Primarily, we hope by bringing these research opportunities to clinicians in a variety of settings, such as community hospitals, substance abuse clinics, private physicians' offices, and community clinics, that we will increase the population base of persons participating in HIV-related research as well as bring research opportunities to persons currently underrepresented in these research projects; specifically members of minority groups, women at risk and persons who use IV drugs. By placing research capability in the hands of community clinicians we also hope to encourage participation by persons unfamiliar or uncomfortable with research conducted by universities or medical centers. Similarly, research conducted by family clinicians or by organizations and facilities with which patients are familiar and comfortable may contribute to truthful representation of use of "underground" drugs or agents thought to be helpful in HIV disease, a major confounding factor of much current HIV-related research. Another major advantage of an active community-based AIDS research program will be the ability to have access to large numbers of persons for various important HIV-related clinical research projects which may be better conducted at a community level.

It is important to reemphasize that the vast majority of persons with HIV infection are cared for by their family physician or in their neighborhood health center. Community physicians and nurses who care for a large number of HIV infected persons have developed significant expertise in the day-to-day management of the full gamut of HIV-related disorders. By establishing a community-based AIDS research program and placing the research agenda of this program in the hands of the community clinicians we expect to make rapid advancements in the standards of care for all persons with HIV infection.

The first CPCRA contracts will be awarded in late summer 1989. Thus, we are unable to comment on the level of science conducted by this program. However, we are confident that the mechanism being

established by the Community Clinical Research Section of the AIDS program to bring technical and administrative assistance to community clinicians in the development of scientifically sound clinical research protocols as well as the process for clearance of all CPCRA protocols through the NIAID Clinical Trials Committee will ensure the conduct of clinical research of the highest scientific quality.

ACCURACY OF CLINICAL TRIALS

Question. Are you satisfied with the accuracy of your clinical trials? For example, the Committee has heard that the clinical trial to determine whether the drug AZT can prevent or delay the onset of AIDS may be jeopardized because patients are cheating by taking other "underground" drugs or by surreptitiously determining whether they are receiving the drug or not, and if not, dropping out of the program or obtaining AZT from other sources.

Answer. While we are troubled by the magnitude of the problem of non-compliance with protocol-prescribed treatment which is occurring in our clinical trials, it is not a problem which threatens either the quality or the accuracy of study results. There are ways to compensate for non-compliance both at the time of study design and analysis. For example, in the case of the specific study referred to in the question, the protocol calls for testing drug levels in study patients as a means for measuring compliance with study medication. It has also been necessary to expand the number of subjects studied, in order to compensate for those who deviate from the protocol.

On a more general level, it is important to understand the origin of this problem because it suggests some possible solutions. Clinical trials are experiments in which we attempt to measure the effect of a new treatment in a group of people. In order to minimize the sources of error, clinical trials, just like laboratory experiments, are designed to follow a specific plan described in the study protocol. The failure of all subjects enrolled in the study to adhere to the protocol is always an issue in any clinical trial, because it is often neither ethical nor medically sensible to force adherence. In AIDS/HIV clinical trials non-compliance is a larger problem than in other disease settings, primarily because patients have few treatment alternatives available to them. The result is that people agree to participate in trials because it is the only way to gain access to investigational new treatments. For a larger fraction of patients than is the case in other settings, this motivation outweighs others which make protocol compliance an important priority.

MAJOR NON-AIDS CLINICAL TRIALS READY TO START BUT NOT FUNDED

Question. I have a list of 8 clinical trials, several for the development of childhood vaccines that you could start in FY 1990 if funds were made available. Please tell the Committee of the several clinical trials that you could start in FY 1990 if funding were available.

Answer. The following clinical trials are ready to begin if funds were available:

- Efficacy Trial for Acellular Pertussis Vaccines
- Efficacy Trial of Childhood Asthma
- Efficacy Trial of Live, Attenuated, Quadravalent, Oral Rotavirus Vaccine
- Efficacy Trial of Influenza A Vaccines
- Efficacy Trial of Hib Conjugate Vaccines
- Therapy for Neonatal Herpes
- Efficacy Trial for Genital Herpes Vaccine
- Hepatitis with Ribaviran

COMMON COLD

Question. Dr. Fauci, I know President Bush cited you as a national hero. But just to keep you humble I know you also have responsibility for finding a cure for the common cold. What progress are you making?

Answer. The common cold can be caused by a number of viruses including rhinoviruses, respiratory syncytial viruses, parainfluenza viruses, coronaviruses, influenza viruses, and adenoviruses. Rhinoviruses, however, are estimated to cause over 50 percent of all common colds. Over 100 different rhinoviruses have been identified, making conventional vaccines impractical. Alternative approaches, primarily targeted antiviral drug development, have been actively pursued by NIAID investigators. X-ray crystallographic analysis of this structurally small class of viruses have identified a structural feature common to all the rhinoviruses. In conjunction with industry-supported scientists, a class of drugs have been developed which effectively block the viral replication in animal models. An Investigational New Drug application has been filed with the Food and Drug Administration to assess the value of this drug in humans. More recently, NIH supported scientists have identified a common cellular component to which the majority of rhinoviruses attach. It is through this process that the rhinoviruses can enter cells, replicate, and trigger the clinical symptoms known as "the common cold." This protein receptor has been isolated from the cells and is known as ICAM-1. When the purified ICAM-1 molecule is added to rhinoviruses before they encounter cells, it prevents the rhinoviruses from attaching and entering the cells. Although there is much to be done in using this information to formulate a safe drug for human use, this is clearly an important finding.

PEDIATRIC AIDS

Question. Dr. Fauci, when you testified several weeks ago with the AIDS panel you indicated that there were several unfunded pediatric AIDS research opportunities. Could you now or for the record tell the committee what these opportunities are?

Answer. There is at present an increasing need for both effective treatment for infected children to delay progression or lessen the severity of their infection, and also for an effective method for prevention of the transmission of HIV from mother to fetus.

The AIDS program of the NIAID is addressing HIV infection through several avenues. The design of strategies targeted at blocking transmission of HIV infection from mother to child requires

knowledge of the natural history of HIV disease in pregnancy and an understanding of any risk factors such as associated illnesses or conditions which may alter the likelihood of passing the infection to the unborn child. The development of therapeutic agents for the treatment of HIV-infected children requires a greater understanding of the natural progression of the disease in the absence of treatment. These are the goals of an epidemiological study being conducted in collaboration with the NICHD. The development of therapeutic strategies using drugs is being carried out within the ACTG under cooperative agreements with a number of clinical investigators around the country.

The NIAID/NICHD Collaborative Perinatal Study was initiated in FY 1988 with contracts to the University of Illinois, University of Puerto Rico, Presbyterian Hospital/Columbia University, and Brigham and Women's Hospital consortium. Its major goals are to:

- Describe the natural history of pregnancy among HIV-infected women.
- Describe the natural history of HIV infection in pregnancy.
- Identify risk factors which influence infection of fetus or infant.
- Describe the natural history of children born to HIV-infected mothers.

To date, at least ten working groups have been assembled to guide the technical progress of the investigations, and the final unified study protocols were completed in February and March. Patient recruitment will be initiated in June. Mothers, potential mothers, and infants and toddlers under age five years will be studied, with a goal of inclusion of at least 500 seropositive mothers.

Because of the proven efficacy of AZT in adults with AIDS, the emphasis has thus far been on the application of AZT in pediatrics. However, protocols for the study of several promising new agents are in development. It has been the traditional practice not to study new drugs in children until they had been proven safe and efficacious in adults. Because of the very poor prognosis of children with symptomatic HIV infection and the absence of a proven therapy which can prevent the death of these patients; the AIDS program plans to conduct early trials of appropriate new agents as soon as practical after initial experience with them has been gained in adults. Thus, if a new agent should prove to be clinically useful in adults there would not be a long delay in moving the therapy into children.

The majority of children receive their infection by transmission from the mother. This transmission could occur in utero, at the time of delivery, or in some cases through breast feeding. It is not known which mechanism is most common. There is evidence that AZT and other antiretroviral agents may prevent the transmission of retroviruses in animals treated with drugs at or shortly after the time of infection. The possibility exists that appropriate treatment of the mother with an antiretroviral agent during pregnancy, treatment of the child immediately after birth, or both may alter the chance of transmission of the HIV to the child.

Clinical trials to address the safety and efficacy of this approach are now being designed within the ACTG.

Question. Do you believe that drug treatment and other services for children with AIDS lag far behind those for adults?

Answer. The evaluation of drug treatment for children with AIDS lags somewhat behind that for adults. It is becoming clear that AZT provides benefits for children similar to that provided for adults with AIDS. Other anti retroviral agents are currently being evaluated in children. The provision of health care services for children with AIDS is becoming a major problem. While it is not clear that these services lag behind those for adults, there is a great need for increased services for both children and adults with AIDS and HIV infection, particularly those in medically underserved communities. A particular need is the lack of extended care facilities for children with HIV who live in an acute care hospital for lack of foster care.

SURVEY OF SEXUAL BEHAVIOR

Question. Dr. Fauci, as you know the National Institute for Child Health and Human Development has the lead in a major $15 million national survey of sexual habits and attitudes of Americans. The study has been justified in part by explaining how the findings could help control the spread of AIDS. Is this study important to the campaign against AIDS?

Answer. Yes, this study is important in the campaign against AIDS. The study is targeted to gain information primarily to help us respond appropriately to the AIDS epidemic. As Dr. Alexander stated in his Senate testimony, every organization and group that has been asked to look at the AIDS epidemic and an appropriate response to it has pointed out that we lack basic information on sexual behaviors in this country. What we know is based on data collected about 40 years ago. In order to project estimates of the spread of the disease as well as to direct our efforts at containing its spread we require much better and up to date information.

LYME DISEASE

Question. The Allergy Institute and the Arthritis Institute both have responsibility for Lyme disease. Which Institute has the lead and how are your efforts coordinated?

Answer. The NIAID is studying Lyme disease since our mission is the study of infectious diseases and NIAID is supporting the majority of NIH-funded Lyme borreliosis research. However, NIAMS also plays a major role in supporting Lyme borreliosis research since various forms of both skin diseases and arthritis are cardinal features of Lyme borreliosis in both early and late stages. Therefore, it would be fair to say that NIAID and NIAMS are the lead Institutes in supporting and encouraging research on Lyme borreliosis.

The NIAID and NIAMS are in close communications with one another and maintain a cooperative effort to ensure efficient use of Federal resources in the battle against Lyme borreliosis. The two

Institutes have co-sponsored an international workshop on Lyme borreliosis that was held in Bethesda last December. Both Institutes are currently co-sponsoring a $2,000,000 RFA on research on the pathogenesis of Lyme borreliosis. Meetings between NIAID and NIAMS staff have been held frequently to coordinate future funding of Lyme borreliosis research by NIAID and NIAMS. Recently NIAID and NIAMS staff members gave a joint presentation on NIH involvement in Lyme borreliosis research at the Lyme Disease Conference held in Austin, Texas.

Question What are the most promising research opportunities for controlling the spread and curing Lyme disease?

Answer. The most promising area for controlling Lyme borreliosis is pathogenesis research. We do not understand how the causative agent interacts with the human host or how the human host responds to infection. Greater understanding in this area will greatly increase our ability to efficiently diagnose the disease; improve the efficacy of treatment; and lead to the development of an effective vaccine. The NIAID interest in this area of research has been communicated to the scientific and medical community through the issuance of an RFA co-sponsored by the NIAMS.

Another promising area is research on the life cycle of the causative agent, Borrelia burgdorferi. Research on the relationship of Borrelia burgdorferi with its animal vectors and reservoirs and on the biology of these vectors and reservoirs will lead to increased ability to control the transmission of Lyme borreliosis to humans and their domesticated animals. The NIAID interest in supporting research in this area has been communicated to the scientific community through the issuance of a Program Announcement.

CENTERS FOR AIDS RESEARCH

Question. What is the focus of research at the seven Centers for AIDS Research which were established in FY 1988?

Answer. The Centers for AIDS Research (CFAR) program is designed to promote the development of new scientific knowledge about AIDS, with the ultimate goal of improving the diagnosis, treatment, and prevention of AIDS. The CFAR program is unique in that the award is a core support grant intended for groups of established investigators conducting AIDS and AIDS-related research which is already funded by NIAID and other Institutes of the NIH. The CFAR award is designed to support activities that will consolidate and focus AIDS research into a coordinated administrative and scientific structure. A typical CFAR award supports several core facilities, provides developmental funds to recruit new investigators into the Center, and provides support for administration, planning, and evaluation. Funds may also be requested for alterations and renovations for upgrading laboratories and providing proper containment facilities for working with HIV and related retroviruses. Research being supported by the CFARs includes structural studies of HIV and related retroviruses, mechanisms by which HIV establishes infection; mechanisms by which HIV causes disease; epidemiologic studies of HIV; preclinical research on development of vaccines and therapy for HIV infection; and research on opportunistic infections associated with AIDS.

COMMUNITY BASED CLINICAL TRIAL PROGRAM

Question. Please describe and explain how NIAID's new community based clinical trial program is functioning.

Answer. On January 17, 1989, we issued a Request for Proposals (RFP) to establish, as a pilot program, the Community Programs for Clinical Research on AIDS (CPCRA). This solicitation is intended to establish a mechanism to deliver administrative and technical assistance to community physicians, community clinics, substance abuse treatment facilities, minority medical clinics or groups of clinicians who care for large numbers of human immunodeficiency virus (HIV) infected persons who wish to become involved in HIV-related clinical projects. Only one month later, February 17, we had received over 700 requests for this RFP, by far, the largest response ever received to any NIAID solicitation. The due date for these proposals was April 17. At this time we do not know the exact number of potentially qualified offerors but early indication is that the response to this concept is overwhelmingly strong. We expect to award these contracts for the establishment of these pilot programs by late summer.

The structure of the CPCRA is designed with flexibility so a variety of programs can be supported in a variety of community situations. We recognize that a wide diversity of experience and preparedness to do clinical research exists on the community level. Accordingly, the CPCRA is designed to offer administrative and technical expertise relevant to the needs of particular communities as assessed by the community providers. An organization or community hospital or substance abuse clinic or neighborhood health center may apply for either Stage I or Stage II support through the CPCRA. Stage I contracts will be established for those programs which feel they need to establish a research capability. They may use this support to hire required staff, such as research nurses, an administrator or social workers, rent space, or purchase computers all of which are intended to be used to establish a capability to perform community clinical research projects. The bulk of the work of Stage I contractors will be attending a series of workshops designed by NIAID to assist community providers in learning the necessary fundamentals of clinical research such as protocol development, data collection and quality assurance; contracts management; FDA and regulatory requirements; and human subject and privacy act protection. At the end of Stage I, contractors will be expected to perform at least one community clinical research project in order to demonstrate their ability. If they successfully achieve the goals of that clinical research project, the government will exercise its option to extend the contract to a Stage II effort for the continuing conduct of community clinical research projects. Organizations which have an existing capability to perform these kinds of clinical research projects may apply directly for Stage II support. During Stage II support, contractors may conduct up to seven community clinical research projects.

It is the intent of the Community Programs for Clinical Research on AIDS to involve clinicians who serve the primary care needs of minority community members with HIV infection. In soliciting proposals for this program we recognized that the providers on the "front lines" of the AIDS epidemic frequently are

not in "the loop" of information about the availability of NIH supported research projects. This is certainly true for clinicians who serve the health care needs of black and Hispanic communities. Accordingly, we publicized the availability of this program outside the traditional research channels by sending information on the CPCRA to nearly 4,000 health providers across the country. This list of providers was designed specifically to reach those clinicians who serve the minority communities of the country as well as those who care for many persons with HIV infection. We also targeted minority medical and health professions' institutions and professional groups. The proposals for the CPCRA will soon be submitted and subject to peer review. Selection of those proposals considered technically qualified is the responsibility of that peer review committee. In this process too, we recognized that an appropriate "peer" committee must include community clinicians, persons familiar with the health needs of blacks and Hispanics and persons expert in the specific health concerns of persons with HIV infection as well as clinical research, medical and social needs of persons who use IV drugs. We hope by convening this peer committee of persons truly representative of community clinicians and relevant HIV concerns that the perspectives of minority clinicians will be recognized and addressed appropriately.

Question. What AIDS drugs are being evaluated in this new program?

Answer. The first Community Programs for Clinical Research on AIDS contracts will be awarded in late summer 1989. Thus we do not know what drugs or protocols will be suggested for testing by those community clinicians who are awarded these contracts.

Question. Do you anticipate that such a program will have any effect on the cheating by patients which is occurring in AIDS clinical trials?

Answer. It is unclear whether the Community Programs for Clinical Research will have any effect on the problem of protocol compliance. Certainly, a major confounding variable of current HIV-related research is the surreptitious use of various drugs or products or "ad hoc" therapies thought to be of use against HIV disease. We expect the longstanding relationship of these providers supported by the Community Programs for Clinical Research on AIDS (CPCRA) to individuals in these communities will significantly contribute to higher levels of openness and honesty. The CPCRA will bring HIV-related research opportunities to family clinicians or organizations and facilities with which patients are familiar and comfortable and thus a major advantage will be the more truthful representation of use of "underground" drugs or agents thought to be helpful in HIV disease. In fact we hope, through the CPCRA, to systematically collect clinical information on the use and effects of some of these products which are in wide use but are untested.

AIDS CLINICAL TRIAL INFORMATION DISSEMINATION

Question. Has NIAID been successful in implementing the first phase of the AIDS Clinical Trials Information Dissemination program?

Answer. The NIAID has established a new, computerized AIDS Clinical Trials Information Service. The service will provide current information, free of charge, about clinical trials sponsored by the NIH for AIDS patients and others infected with HIV.

Physicians and other health practitioners, as well as patients and their families, may call the service for specific information about NIH-sponsored clinical trials of experimental therapies for AIDS and AIDS-related diseases. Callers will be linked with experienced health specialists who will access an online data base offering the most up-to-date and complete information on more than 60 studies.

Callers will be provided with specific information on various study options, including eligibility requirements, exclusion criteria, study location and duration, and names and telephone numbers of contacts at each study site. Brief descriptions of specific experimental therapies being studied by NIAID and other NIH institutes will be available and the information will be updated every week.

Information will be provided directly and immediately by telephone, and callers may talk with a Spanish-speaking health specialist. All communication with the service will be completely confidential. On request, callers may also obtain computer printouts from custom searches of the data base. In addition, plans are underway to make the information available through the National Library of Medicine's online services.

The AIDS Clinical Trials Information Service is sponsored by NIAID in cooperation with the Centers for Disease Control.

Question. Do you anticipate that such a program will have any effect on the cheating by patients which is occurring in AIDS clinical trials?

Answer. It is not clear to us that the Clinical Trials Information Service will have an effect on the problem of protocol compliance. If an effect is seen it might be beneficial, since potential subjects would be armed with more information and would be able to choose to participate in studies from a more accurately informed starting point.

FUNDING FOR AIDS RESEARCH

Question. Is the amount of funding for AIDS research being provided by NIAID exceeding the ability of scientists to design valuable experiments?

Answer. The amount of funding for AIDS research being provided by the NIAID is not exceeding the ability of scientists to develop worthwhile and valuable research projects. While funding levels for AIDS research have increased steadily and substantially over the past few years, there remain a large number of scientifically meritorious projects which cannot be funded. With regard to investigator-initiated research project grants, a significant number of applications have been approved and have received priority scores which represent good quality science but which are not in the

fundable range. In addition, a number of programs in which additional investigators could participate and are needed, have insufficient funds to support all the scientifically meritorious applications or contract proposals.

Question. Is the large amount of funding available for AIDS research causing NIAID to fund research proposals with significantly lower scores than other areas of research?

Answer. The operating payline for the NIAID is the same for AIDS research and for research other than AIDS. Because of the availability of additional funding specifically for AIDS research, it has been possible to selectively pay a larger number of AIDS grants that are outside the payline than is the case for research other than AIDS. Because a larger number of AIDS grants can be selectively paid, the average score of funded grants is higher than those for research other than AIDS. All those AIDS grants funded, however, have received scores indicative of excellent quality research. Each AIDS grant under consideration for selective pay is carefully considered by NIAID staff to confirm that it is of high scientific quality and of high relevance to the AIDS program of the Institute.

TRANSFUSION-RELATED NON-A NON-B HEPATITIS

Question. What is the status of the development of a diagnostic test which will be used to screen donated blood for infection with non-A non-B hepatitis virus?

Answer. Chiron Corporation and Ortho Diagnostics are now evaluating an antibody test for its ability to determine the presence and amount of antibody to the virus causing blood-born non-A non-B (NANB) hepatitis. This work which should be complete by the summer will look at the sensitivity and specificity of the candidate test. The companies are expected to file for licensure if the results of the evaluation warrant this step.

Question. Has the Small Business Innovation Research program, which funded a majority of the work on this non-A non-B project, been involved in any other research advances at NIAID?

Answer. The Small Business Innovation Research Program (SBIR) has provided support for the development of a number of diagnostic tests, including a test used to screen donated blood for infection with non-A non-B hepatitis virus. This program has also been the vehicle for a number of other significant advances in biomedical research, including:

-Rapid diagnostic test for human fungal pathogens
-Molecular diagnostics for Epstein-Barr virus
-DNA probe diagnosis of sexually transmitted infections
-Production of reference agents for Simian AIDS and STLV-III
-Genetic engineering approaches to AIDS vaccines
-Genetic engineering approaches to malaria vaccines
-Isolation of bulk deoxynucleotides for AIDS drugs

This program will continue to provide opportunities for small businesses to make major contributions in this nation's biomedical research endeavors.

LYME DISEASE

Question. Is NIAID involved in any programs to educate physicians on the symptoms of Lyme disease?

Answer. At present there are no NIAID-sponsored programs aimed at educating physicians on Lyme borreliosis. However, plans are in progress for the development of a health care professional-oriented educational program. This is a project that has been recommended by Dr. Willy Burgdorfer of the NIAID Rocky Mountain Laboratories for consideration as a high priority.

Question. What programs, such as the national workshop on Lyme disease which NIAID is co-sponsoring, have been developed by NIAID to stimulate research in this important emerging area?

Answer. NIAID has published two Lyme borreliosis initiatives designed to stimulate research. In cooperation with the NIAMS, NIAID has issued an RFA for research on the pathogenesis of Lyme borreliosis. Each Institute has budgeted $1,000,000 per year for five years to support the best research applications submitted in response to this RFA.

The NIAID has also issued a Program Announcement indicating the Institute's interest in supporting research on the epizootiology and transmission of Lyme borreliosis. Research in these areas will increase our understanding of the life cycle of the causative agent in the environment and will result in more effective approaches in the control of transmission of the disease to humans and domestic animals.

TUBERCULOSIS DETENTION, TREATMENT, AND VACCINATION

Question. Dr. Fauci, can you please give us an update on the action your institute has taken to develop more sophisticated means of detection, treatment, and vaccination for tuberculosis?

Answer. NIAID continues to encourage basic research on all aspects of tuberculosis. The Institute funds recombinant DNA research with the objective of creating a more effective vaccine against tuberculosis. Other ongoing research deals with the isolation of M. tuberculosis protein antigens to be used in the development of more effective diagnostic tests. As a result of a recent RFA, the NIAID has funded five highly meritorious tuberculosis research grants and hopefully will be able to fund additional meritorious tuberculosis grant applications from the same RFA. The Institute plans to continue to stimulate research on more sophisticated means of detection, treatment and vaccination for tuberculosis.

PREVENTION OF BLINDNESS IN AIDS PATIENTS

Question. We have read a great deal about the use of "DHPG" for prevention of blindness in patients with AIDS. Could you please

give us an idea of the status of any trials that you have for this drug? Is this drug readily available to the public?

Answer. Within the AIDS clinical trials network sponsored by the NIAID AIDS program, ganciclovir is being tested in several ways. A study being conducted by NIAID clinical trials sites, as well as sites sponsored by Syntex, is examining the effectiveness of this agent as immediate vs. deferred therapy in patients with peripheral retinitis. Another NIAID-sponsored clinical trial compares ganciclovir as a single agent to combination therapy with ganciclovir and granulocyte macrophage colony stimulating factor (GMCSF) for patients with sight-threatening retinitis. Another protocol being finalized will involve a pilot study of intravitreal ganciclovir as salvage therapy. In addition, the NIAID AIDS program is sponsoring a Treatment IND protocol which makes this drug available to physicians nationwide for patients with sight-threatening retinitis. As of April 1989, 575 patients have been entered into this protocol, with weekly accrual averaging 44 patients.

ASTHMA MORTALITY

Question. Dr. Fauci, We understand that there is an increase in asthma mortality. Will the President's budget allow you to adequately respond to the needs in this area?

Answer. While there has been a reported increase in asthma mortality, it should be noted that a large portion of this increase has occurred among persons 65 years of age and older. In addition there has been a disturbing increase in prevalence of asthma among urban minority populations in New York City, Chicago, Baltimore and the District of Columbia.

Within the President's budget we will be able to continue several small programs which are ongoing in Los Angeles, Baltimore and Washington, D.C. which aim to specifically address the problem of asthma in our adolescent population. We will be unable to launch a planned clinical trial which would bring modern and comprehensive medical management of asthma to this population.

BASIC IMMUNOLOGY

Question. Dr. Fauci, your Institute has the responsibility for research on basic immunology. Do you have anything new to report from your institute in this area?

Answer. Research in the field of basic immunology is one of the most-productive and rapidly-moving areas of investigation. It is not possible to delineate everything we have been able to accomplish, however, I can provide a few examples of developments in this area.

Molecular complexes called "T-cell receptors" play a pivotal role in the immune-system by determining immune response to foreign antigen exposure and by regulating and controlling those T cells which cause antibodies against "self." Without this regulatory control we would all suffer from devastating autoimmune diseases such as systemic lupus erythematosis or rheumatoid arthritis for

example. The recent elucidation of the structural chemistry of T cell receptors combined with the discovery of the mechanisms that activate the expression of selective genes in T cells which produce lymphokines will permit the development of specific regulators of immune responses. Hopefully this knowledge will permit us to devise methods to restore certain deficiency responses as well as to inhibit certain undesirable ones.

Progress in elucidating the chemistry and biological functions of lymphokines has been rapid. Lymphokines are soluble substances in our blood stream which can regulate immune responses. The genes encoding most of the lymphokines have been identified and recombinant lymphokines are now available for clinical testing. Several of the lymphokines have been broken down into active fragments and work is in progress to produce fragments that can be used clinically like conventional drugs. The variety of prospective clinical uses for the lymphokines and their derivatives include the treatment of allergic diseases including asthma and hay fever; immunodeficiency disease; microbial infections including AIDS; and various forms of cancer.

The identification and isolation in pure, or nearly-pure, condition of murine hematopoietic stem cells has been achieved. These cells have the potential to regenerate all of the various types of normal blood cells including the lymphocytes of the immune system. We are well along in the isolation of the human stem cells in pure state. The way is now open to investigations that will have far-reaching significance. For example, stem cell therapy in patients suffering from immunodeficiency and autoimmune diseases, cancers, and anemias. It should be possible soon to treat patients intentionally, in preparation for certain organ or tissue grafts, or accidentally exposed to ionizing radiation, or severely toxic substances, by defined stem cell therapy.

QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

TUBERCULOSIS

Question. Secretary Sullivan has endorsed the HHS Advisory Committee goal of eliminating tuberculosis from the U.S. by the year 2010. What role will your Institute play in meeting this goal? In your judgment, is the research on tuberculosis vaccines, anti-tuberculosis drugs, and tuberculosis diagnostic tests being funded adequately?

Answer. The HHS Advisory Committee's "Strategic Plan for the Elimination of Tuberculosis in the United States" outlines specific research in various areas that must be successfully completed. The specific areas are divided into basic, applied, and epidemiologic/operational research. NIAID is responsible for the extensive basic research that is outlined in the plan. The Institute is presently funding a very small portion of the research outlined in the plan, and will continue to provide support as funds become available.

Question. Would promising research project proposals in these areas go unfunded under the FY 1990 budget request?

Answer. Many promising research proposals for research on tuberculosis vaccines, anti-tuberculosis drugs, and tuberculosis diagnostic tests will not be funded under the FY 1990 budget request.

Question. NIAID receives the lion's share of funds for AIDS research. I assume that increase in funding has meant an overall increase in the number of new and competing grants awarded by your institute. I am most interested, however, in the number of new and competing non-AIDS grants awarded by NIAID in the last several years. Could you share that information with the Committee? What level of funding would you need to return to FY 1988 levels of new and competing awards.

Answer. The number of new and competing research project grants which we have been able or will be able to fund is as follows:

	FY 1988	FY 1989	FY 1990
Research Project Grants	520	453	313

We would require approximately $101,427,560 in our competing grant budget to fully fund 520 research project grants in FY 1990.

Question. Has research on tuberculosis vaccines and treatments been affected by this reduction in new and competing grants? Research on treatment for Hepatitis B virus? Research on the treatment and prevention of sexually transmitted diseases?

Answer. A reduction in the number of new and competing grants will result in a reduction of our research on the development of new tuberculosis vaccines, research on Hepatitis B and research on the treatment and prevention of sexually transmitted diseases.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

NON-AIDS RESEARCH

Question. Dr. Fauci, I am informed that over the last few years the number of new and competing grants for the non-AIDS research funded by the NIAID, particularly in the area of basic research immunology, has been drastically reduced. For the record would you provide an overview of the funding levels (and number of new and competing grants awarded) for the non-AIDS research at the NIAID from FY 1986 to the present FY 1990 request?

Answer. The following are the number of new and competing research project grants and the funding levels in thousands of dollars for those grants for the period FY 1986 to FY 1990:

	FY 1986	FY 1987	FY 1988	FY 1989	FY 1990
Number of grants	549	496	520	453	313
Funding level	$80,613	$78,960	$83,007	$68,952	$51,219

Question. How much does the NIAID need in FY 1990 to fund non-AIDS approved new and competing grants at a 50 percent award rate?

Answer. The NIAID needs approximately $171,843,000 to fully fund new and competing research project grants at a 50 percent award rate in FY 1990.

Question. How much is included in the President's FY 1990 request?

Answer. The FY 1990 President's Budget includes $51,219,000 for new and competing research project grants.

Question. How much does the NIAID need to fully fund the non-competing non-AIDS research project grants in FY 1990?

Answer. The NIAID needs approximately $271,038,000 to fully fund noncompeting research project grants in FY 1990.

Question. How much is included in the President's request?

Answer. The FY 1990 President's Budget includes $251,002,000 for noncompeting research project grants.

Question. Dr. Fauci, what was the original NIAID request for FTE's in FY 1990 for non-AIDS?

Answer. The NIAID's request for FTE's in FY 1990 was 758, or an increase of 117 over our FY 1989 ceiling of 641.

Question. How many are included in the President's request?

Answer. The number of FTE's included in the FY 1990 allocation from DHHS totals 632.

Question. How many did you request for AIDS?

Answer. The NIAID request for FTE's for AIDS research in FY 1990 was 478.

Question. How many are included in the President's request?

Answer. The FTE's included in the FY 1990 allocation from DHHS totals 263.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next let's go to the National Institute of Neurological Disorders and Stroke, and Dr. Goldstein.

Dr. GOLDSTEIN. Thank you, Senator Harkin.

As you know, sir, the NINDS is the focal point at the NIH for neuroscience research, basic and clinical research on the brain, the spinal cord, and other parts of the nervous system.

There are 600 neurological diseases, and it would take an inordinate amount of time to even attempt to summarize the progress being made. So let me just discuss a few examples of the highlights in the time available.

STROKE

One is stroke. Stroke remains the third leading cause of death in the country.

During the last 10 years, the incidence of new cases of stroke fell regularly. We were delighted with that progress and felt rather proud of the results of our efforts. But I'm sorry to say hard data are now available to show that the current stroke rate per 100,000 population is again going up.

It is a rather startling finding.

Senator HARKIN. It's going up again?

Dr. GOLDSTEIN. That's right, sir. Two independent studies have documented this, and we are looking very hard at why this is occurring.

We now have some theories as to why this is happening and are exploring those possibilities in depth. But I do bring this to your attention. The occurrence of new cases of stroke in all populations, male and female, minority, black and white, are going up in all of these population groups.

So we need to address this finding with a great deal of emphasis and attention.

HEAD INJURY

Second, I would like to bring to your attention another disorder which is, in fact, a national emergency, and that is head injury. Every 15 seconds in this country, somebody is head injured. Every 5 minutes, somebody in this country dies due to a head injury.

It is the leading cause of death between the ages of 1 and 40. More people die of head injury than any other single cause. It is a disastrous thing.

Those who do survive are often delegated to a lifetime of lack of ability to learn, to poor speech, and inability to perform in our society. It is a national tragedy.

Senator HARKIN. May I interrupt you right here?

Dr. GOLDSTEIN. Pardon me, sir?

Senator HARKIN. May I interrupt you right at this point?

Dr. GOLDSTEIN. Please.

Senator HARKIN. I am very interested in this.

My notes say that it is the fourth leading cause of death. It is the first leading cause of death among those ages 8 to 27, is that the figure?

Dr. GOLDSTEIN. No; it's the ages of 1 to 40, sir.

Senator HARKIN. Ages 1 to 40?

Dr. GOLDSTEIN. That's correct, sir.

Senator HARKIN. It's the leading cause of death?

Dr. GOLDSTEIN. In this country.

Senator HARKIN. All right. Then you must have some data as to what causes head injuries.

Dr. GOLDSTEIN. Yes, sir.

Senator HARKIN. What is the leading cause?

Dr. GOLDSTEIN. I just happen to have the figures here. One-half are due to motor vehicles, 50 percent.

Senator HARKIN. So 50 percent are motor vehicles.

Dr. GOLDSTEIN. Yes; motor vehicle accidents.

Then, 21 percent are due to falls.

Senator HARKIN. So 21 percent are falls.

Dr. GOLDSTEIN. Next, 12 percent are due to assault and violence; 10 percent are due to sports and recreation.

Interestingly enough, in infants, 64 percent are due to child abuse.

Senator HARKIN. That's 64 percent?

Dr. GOLDSTEIN. Yes; 64 percent are due to child abuse.

Senator HARKIN. That's 64 percent of incidences of head injury?

Dr. GOLDSTEIN. Yes; 64 percent of head injury in infants are due to child abuse.

Senator HARKIN. When you say child, what ages?

Dr. GOLDSTEIN. I'm sorry, but I don't have that figure.

Senator HARKIN. But 64 percent of head injuries in children are due to child abuse.

Dr. GOLDSTEIN. Yes; 64 percent are due to child abuse in infants. That is as specific a statistic as I can give you.

Senator HARKIN. So 50 percent is motor vehicles. Do you have a breakdown between cars and motorcycles on that.

Dr. GOLDSTEIN. No; I don't. I can try to supply that for the record, sir, but I don't have the data at this time.

[The information follows:]

MOTOR VEHICLE RELATED HEAD INJURY

Of 500,000 persons having severe enough head injury to require hospital admission, approximately 250,000 were due to automobile accidents and 7,000 due to motorcycle accidents.

FALLS

Senator HARKIN. Falls are 21 percent.

Dr. GOLDSTEIN. Yes; 21 percent due to falls; 12 percent due to assaults and violence; and 10 percent due to sports and recreation.

A very sensitive issue, of course, is boxing. It is the only sport in our society whose primary and only objective is to damage the brain.

Senator HARKIN. I never thought about that, you know.

Dr. GOLDSTEIN. I am referring to a knockout blow. That is the objective of boxing, to knock the opponent out. You cannot knock somebody out without damaging his brain.

Senator HARKIN. I just never thought of it in that way, but you are right.

People always say well, boxing and football. You get injured in football, too. But that is not the primary reason of football.

Dr. GOLDSTEIN. Exactly.

Senator HARKIN. The primary reason of boxing is to inflict head injury.

Dr. GOLDSTEIN. To knock somebody out. When you knock him out, you've damaged his brain.

Now, in other sports, football and soccer with the hitting of the head, there are obvious things that can occur to the brain. But brain injury is not the objective of the game.

I won't comment on hockey. That sometimes gets a little peculiar because of personal assaults. [General laughter.]

Senator HARKIN. No one understands what the primary reason for hockey is. [General laughter.]

Dr. GOLDSTEIN. Well, I have given you two examples, sir, of neurological and brain diseases. But I would like to make one other point, and that is this.

BASIC NEUROSCIENCE

In addition to this, the brain is really the last major frontier of medical ignorance. Knowing how the brain works, how do we learn, how do we store information, what is memory, how do we recall information after it has been stored—all the computers available are child's toys when compared with the brain.

PREPARED STATEMENT

Just observe the patient in a coma and we begin to realize what happens when just one part of the brain is turned off. The basic neurosciences are the research arena of today which provide for tomorrow's breakthroughs. Those are the research areas of responsibility of the NINDS, and I would be very pleased to try to respond to any questions you might have.

[The statement follows:]

STATEMENT OF DR. MURRAY GOLDSTEIN

The National Institute of Neurological Disorders and Stroke (NINDS) leads the Federal research effort in both the basic neurosciences and the diseases and disorders that affect the brain and other parts of the nervous system. Neurological disorders due to disease and injury are costly and, too often, devastate our citizens in nearly every age and segment of the U.S. population. Overall, stroke ranks as the third leading cause of death in this country, while traumatic brain injury (TBI) is the leading cause of death and disability in children and young adults. The neurologic effects of AIDS infection have emerged as a major complication for 40-80 percent of all AIDS patients, presenting additional challenges for the treatment of this modern epidemic.

The field of neurology is alive with new opportunities to understand the nervous system and devise optimal approaches to the care and management of patients. The technologies of positron emission tomography (PET) and magnetic resonance imaging (MRI) create extraordinary opportunities to image the function and anatomy of the living brain, with a power and sensitivity not previously available. With these tools, we are planning new investigations into the higher brain functions--memory, learning, language, thinking--to understand how their derangement can result in dementia, autism, and aphasia. These research tools are complemented by advances in the basic neurosciences, including molecular neurobiology, neurogenetics, and neurochemistry, which have greatly increased the pace and extent of neuroscience research. With the ability to study a range of neural activity from the level of the individual cell to the whole brain, vast new areas of the neurosciences can now be explored.

An estimated one-fourth of the 4,000 known genetic disorders affect the nervous system. The effects of missing or defective genes may become apparent soon after birth or during school years--as with Gaucher's disease, Batten's disease, and neurofibromatosis--or the effects may be delayed until patients are well into the prime of their life and are afflicted with various types of stroke, Huntington's disease, Parkinson's disease, or epilepsy. Research into the genetic basis of brain and muscle diseases is crucial to facilitate diagnosis and treatment. For many diseases affecting the nervous and muscular systems, we are just beginning to understand the intricate relationships between genes and the manifestations of symptoms. For instance, recent data suggest that there are different types of Alzheimer's disease, and they are influenced by defects in different genes.

We are pleased that the investment in neuroscience is doubly rewarded because much of the new knowledge gained from the study of neurological models of disease is reflected back to the broader scientific disciplines, such as genetics, immunology, and cell biology. For example, while researchers continue to move in on the precise location of the Huntington disease gene--known to be near the end of chromosome 4--they are uncovering much about the unique properties of this part of chromosomes that is critical to the study of other genetic diseases and to the mapping of the entire human genome. Likewise, research on multiple sclerosis adds to our knowledge of the organization and function of the immune system.

The recent progress in understanding some types of muscular dystrophy is also an example of the success that may be achieved with a commitment of talented investigators and resources, and demonstrates the step-wise progress of neurological research. A few years ago, neuroscientists successfully isolated the gene responsible for Duchenne's muscular dystrophy. The gene is relatively large--one of the largest yet discovered. Mutations at different points on the gene produce different symptoms and, in fact, we now know that a defect in one part of the gene is responsible for what we previously thought was another disease, Becker's muscular dystrophy. Soon after the gene was discovered neuroscientists identified a protein made by the gene and, most recently, have learned that this protein, dystrophin, is present in normal muscle cells but is absent or greatly reduced in muscle cells from patients with Duchenne's muscular dystrophy. These discoveries have stimulated several lines of investigation. First, investigators immediately worked to develop a test that would measure dystrophin levels and diagnose the disease early, with the expectation that in the future appropriate therapy can be initiated before irreversible damage occurs. However, we still do not know specifically what dystrophin does and scientists are actively working to characterize its role in muscle activity. Obviously, that knowledge will have vital implications for understanding several neuromuscular disorders.

Epilepsy is characterized by seizures--sudden and rapid bursts of electrical activity in the brain that can occur across the whole brain or in isolated parts. Although many events can trigger seizures including head injury, complications from pregnancy, infections, or other diseases, for many people the cause remains unknown. Because epilepsy is not a single disorder, proper treatment depends greatly on understanding the triggering event, the location of the seizure within the brain, and the frequency of seizures, so specific treatment can be matched with the particular patient's pathology. Treatment for epilepsy involves chemical methods to control seizures. On occasion, in patients unresponsive to medication, surgery is necessary to remove the portion of brain tissue from which the seizures originate. The NINDS research effort is multi-faceted, to understand why seizures occur, to improve the clinical management of patients, to identify new compounds with anticonvulsant potential, and to evaluate promising agents in clinical trials. The NINDS anti-epileptic drug development program is the most successful program in this area of pharmacologic research. In addition, progress in epilepsy research has been greatly enhanced with the use of PET and MRI to more precisely localize seizures, monitor therapy, and study the effects of epilepsy on brain metabolism.

We are currently focusing laboratory and clinical research efforts on neonatal seizures which affect low birthweight infants. The newborn presents special problems concerning the diagnosis and treatment of seizures. In most cases, it is not clear if the seizures are a sign of another underlying neurologic problem, or a primary factor contributing to further brain damage. Our goal is to learn more about neonatal seizures so that we can devise methods to intervene and prevent them from occurring, thereby saving these infants from death or a lifetime of disability.

Each year, approximately 500,000 Americans suffer head injuries severe enough to require admission to a hospital; another 10,000 to 12,000 new victims are disabled by trauma to the spinal cord. The costs of care and services for patients with traumatic brain injury approaches $25 billion per year; for the estimated 250,000 to 500,000 survivors of spinal cord injury, it exceeds $2 billion each year. The NINDS leads the Federal research effort against head and spinal cord injury with a broad-based research approach to tackle the problems of diagnosis, acute and long-term clinical care, and restoration of function. These targeted research efforts aimed at helping the patient are intimately tied to basic laboratory investigations of the nervous system's response to trauma and nerve cell growth and repair. This national effort is modest but moving ahead steadily.

The nervous system's initial responses to injury--trauma, stroke, convulsions--cause the release of neurotransmitters and opiate-like compounds to control the bleeding and pain. Ironically, these body chemicals can make the patient's condition and prognosis worse by causing additional cell and tissue damage. We have evidence that this secondary damage partly results when calcium flows into the nerve cells and triggers a cascade of chemical reactions producing substances lethal to the cells. This chain of events presents several critical points at which we plan to be able to intervene and slow or block the destruction. Saving the lives of those with head or spinal injury depends on expanding our knowledge of the body's response to trauma so that improved clinical approaches can be developed. This is an extremely promising area of research with tremendous opportunity for benefit.

Stroke remains a major killer and leading cause of disability in the United States. The very sudden loss of language, feeling, or movement that is characteristic of a stroke results from disrupted blood flow to a part of the brain, due to a blockage or break in a blood vessel, and the resulting lack of oxygen to brain cells. The long-standing NINDS research effort against stroke has contributed to the steady decline in the national stroke death rate--a remarkable 33 percent decline over the past decade--so that more people are surviving the assault of stroke. The good news, unfortunately, is tempered by the fact that each year, hundreds of thousands of Americans still have a stroke. The presence of high blood pressure, diabetes, and other factors continue to put people at a higher risk for stroke. The NINDS research effort against stroke is aimed at improved prevention, diagnostic, and treatment methods. In a major ongoing clinical trial, the efficacy of carotid endarterectomy--a common surgical procedure to remove fatty deposits from the carotid artery in the neck--is being evaluated in comparison to medical therapy.

For any person who has a stroke, the care and treatment received within the first few hours and days determine the chance for survival and functional recovery. For instance, clinical studies demonstrate that in selected patients with strokes due to aneurysm, surgical treatment within 1-3 days of the incident has a greater chance of success. Patients with ruptured aneurysms that bleed into the subarachnoid space between the brain and the skull often experience a special problem that complicates their chance for survival. For reasons not yet understood, these patients are at increased risk of blood vessel spasm for a period of 7-14 days after

the stroke. The vasospasm reduces blood flow and starves the brain cells of oxygen, precipitating another medical crisis for the patient. The NINDS is supporting a multi-center clinical trial to evaluate the effectiveness of a drug called nicardipine to prevent vasospasm.

The NINDS is also exploring several new treatments for people with stroke due to occlusion of a blood vessel. Among the several experimental therapies, one under study is tissue plasminogen activator, or TPA, a clot-dissolving drug currently used to treat heart attack victims. The Institute is supporting a pilot study with TPA to carefully evaluate the optimal dose and determine the feasibility of a full-scale clinical trial. Investigators are also looking at the use of heparinoids to prevent the formation of new clots in certain stroke patients, thereby preventing further tissue damage.

Several lines of investigation offer opportunity to restore or improve function in people who have experienced brain disease or injury. Basic research is illuminating the mechanisms by which nerve cells grow and function, providing insights that may lead to methods to repair and regrow damaged cells in the brain and spinal cord as easily as the body heals other organs. The replacement of nerve cells that have been lost or destroyed also may offer a method to restore the chemical balance necessary for normal brain metabolism. Research on electronic neural prostheses shows promise of restoring movement and urinary bladder control to paralyzed individuals.

The neurological consequences of AIDS--including nerve injury, memory disorders, and dementia--greatly add to the personal suffering caused by AIDS and the difficulty in caring for AIDS patients. The NINDS is attempting to match the limited resources available for neuro-AIDS research against a multitude of questions concerning its etiology, prevention, and treatment. Neurological AIDS studies recently showed that AZT is beneficial in improving memory and motor speed in AIDS patients; its efficacy in treating dementia and preventing neurological symptoms in asymptomatic individuals remains to be addressed. A collaborative study with the National Naval Medical Center will help to answer questions concerning the natural history of neuro-AIDS, particularly in infected but asymptomatic patients.

The basic and clinical neurosciences continue to be research areas of great productivity and opportunity. In these times of fiscal restraint, we have innumerable paths to choose from to further advance the frontiers of the neurosciences in the quest to save lives and improve the quality of life of many Americans affected by brain disorders.

Mr. Chairman, the FY 1990 budget request for this Institute is $477,128,000. I am pleased to answer any questions you might have.

BUDGET REQUEST

Senator HARKIN. Tell me, what is the budget for your institute, and how is it increasing or decreasing?

Dr. GOLDSTEIN. The President's budget for NINDS for fiscal year 1990 is $477,128,000, exclusive of AIDS. AIDS is an additional $16.37 million.

Senator HARKIN. Would you give me that figure again?

Dr. GOLDSTEIN. Yes, sir.

The budget for the Institute, exclusive of AIDS, is $477,128,000; AIDS' allotment is an additional $16,374,000.

Senator HARKIN. How does that compare to last year?

Dr. GOLDSTEIN. It is an increase, sir.

Senator HARKIN. A $22 million increase out of $474 million—that's about 5 percent. Is it something like 5 percent?

Dr. GOLDSTEIN. About that, sir, roughly.

Senator HARKIN. What did you request?

Dr. GOLDSTEIN. The professional judgment budget, sir?

Senator HARKIN. Yes; professional judgment.

Dr. GOLDSTEIN. Without AIDS, the professional judgment budget was $590,130,000. With AIDS, it was $616,430,000. That's $590,130,000; with AIDS, it is $616,430,000.

HEAD INJURY

Senator HARKIN. All right.

Just getting back to the head injury, you chair the Interagency Head Injury Task Force that submitted a report to Congress, which has a number of recommendations for additional head injury research.

Dr. GOLDSTEIN. Yes, sir.

Senator HARKIN. How much are you doing now and what additional things are you looking at?

Dr. GOLDSTEIN. Presently, the Institute is investing approximately $20 million in head injury research. The reason I have to guard my language a little bit is because we also have a spinal cord injury program and a central nervous system regeneration program, which impacts on both head and spinal cord injury. But, in head injury, per se, approximately $20 million.

The Head Injury Task Force Report addresses two major activities in biomedical research. It also addresses rehabilitation, patient care, and patient services nationally.

The report recommends very strongly that 15 regional head injury research centers be established in close coordination with regional head injury care facilities. The report recommends that, as a pilot basis, in the first year, five such centers be established. Those would cost approximately $10 million, with a national objective at the end of 3 years of 15 such centers.

The number of regional centers was based upon the patient population distribution of the country, as well as the scientific support groups that would be available.

But in the first year, the report recommends that there be five such centers, which we believe would cost about $10 million; also, an additional $5 million would be made available for individual research projects of the investigator-initiated research type.

Senator HARKIN. Where are we in terms of spinal cord regeneration or spinal cord injuries?

SPINAL CORD REGENERATION

Dr. GOLDSTEIN. Yes, sir.

There are two separate parts to that question. The first is what do you do when the spinal cord is injured. We now have very, very definitive evidence that if one can intervene within 4 hours of the injury, it may be possible to protect the patient. Let me explain that.

Most spinal cord injuries do not involve a bullet or an object cutting the spinal cord. In fact, what happens is the spinal cord is bruised. Then, for reasons that we still do not completely understand, the body goes about destroying the spinal cord after it has been bruised. It causes what we call a physiological transsection, namely, the body initiates a process that cuts the spinal cord in half, after a bruise.

That process can be arrested within 4 hours.

There are a number of experimental therapies now under trial to stop that process and, hopefully, to reverse it. At the moment, there are three drugs that are being tested in a national protocol.

The second part of the story is what happens after the damage to the person has occurred, to the person who is paraplegic. Will the spinal cord ever grow together again? Will the paraplegic ever be able to walk?

Ten years ago, we knew the answer was no; there was just no question about it. Well, we were wrong. We were absolutely wrong, because now, we can, in fact, in an experimental animal transsect the spinal cord right under the skull, and have the new nerve grow from the brain in a tube as long as we want it to grow—the full length of the cord, a whole yard. The problem is that when we take the tip of that nerve that has grown out from the brain and put it's growing end into the spinal cord, it stops growing immediately. It just stops.

Now, that is a solveable problem. We obviously have some leads.

But there is a second part of that problem which is really much more perplexing; that is how will that nerve know where to go? The terrible example that I use is that if it's supposed to go to your big toe and went to your bladder, you'd have one devil of a problem.

But that nerve knew where to go in the first place. In the genetic code, there was information which said that nerve from that part of the brain must go to that big toe.

That is what we are hard at work on, and that is probably the more difficult question than getting the nerve to continue to grow—namely, to hook it up to the right place.

Senator HARKIN. This is where my ignorance shows, but does the human genome project have any applicability there?

Dr. GOLDSTEIN. Well, in the long run yes, because there must have been a code which sent out the information to the newly developing nerve in the first place, and the issue is is the code still there. Is it operable? Can we start it up again? Can we get it to send out information?

Now, that would be a long-term consequence of genetic research. But we have a long way to go on that one.

Senator HARKIN. Tell me about the latest in stroke and cholesterol. What is happening there? Do we have some positive information now in terms of the effects of cholesterol on heart disease?

STROKE AND CHOLESTEROL

Dr. GOLDSTEIN. There is a controversy raging. When we look at people who develop stroke after the age of 60—and that is most of the people—interestingly enough, blood cholesterol levels do not seem to make a bit of difference. There are some reasons for that.

In white males under the age of 55, high cholesterol levels are a very important risk factor. But once one gets past that age, it does not seem to be important.

Now, the logic on that may be—I don't know that this is true—it is that these are survivors; that once you get to be 58 and 60, and cholesterol has not plugged up your coronary artery system, there are probably good reasons why they don't also plug up the brain vasculer system.

Now, I am not saying—and, please, I want to make a point of this—that high cholesterol is good for you. That, of course, is ridiculous. There are many, many good reasons for lowering elevated cholesterol, but stroke is apparently not one of them once you get to the ages of 55 or 60.

However, smoking has now been recognized as a major risk factor for stroke at all ages, and particularly if one is a female, on contraceptive pills, has high blood pressure, and smokes. These women are going to have a stroke.

THE DECADE OF THE BRAIN

Senator HARKIN. Regarding the brain, the report issued last year entitled "The Decade of the Brain"——

Dr. Goldstein. Yes, sir; I happen to have a copy of it here.

Senator HARKIN [continuing]. Indicated that with recent medical discoveries and new imaging technologies, some of which I have seen, which I think are just remarkable, we are on the verge of major breakthroughs in understanding the brain and its diseases and disorders of the brain.

Even with all of these opportunities, your budget grows only slightly faster than inflation.

How much additional funding do you believe would be necessary to fully meet all of the scientific opportunities outlined in that report?

Dr. GOLDSTEIN In the Decade of the Brain report, sir?

Senator HARKIN. Yes.

Dr. GOLDSTEIN. It's $116 million additional.

Senator HARKIN. That's $116 million additional?

Dr. GOLDSTEIN. Yes, sir.

Senator HARKIN. Do you have the people out there who can do that kind of research?

Dr. GOLDSTEIN. The scientists are there. The scientific opportunities are there. This report describes that in great depth. It is a go/no-go situation.

Senator HARKIN. Was that reflected in the professional judgment budget a moment ago?

Dr. GOLDSTEIN. Yes, sir.

Senator HARKIN. That's where you go from $477 million to $590 million?

Dr. GOLDSTEIN. Yes, sir.

Senator HARKIN. That was the difference?

Dr. GOLDSTEIN. That was it.

We read the report that scientists put together very carefully and tried to cost account it in a reasonable way.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Dr. Goldstein, thank you very much.

Dr. GOLDSTEIN. Thank you very much, sir.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

HEAD INJURY

Question. Every thirty-seconds, someone in America suffers a head injury, half of those injuries, almost 500,000, are serious enough for admission to a hospital, and half of those cases admitted to hospitals result in death and the other half typically result in a permanent disability.

Head injury is the fourth leading cause of death in America and the first leading cause of death among those 8 to 27 years of age. Services for patients with traumatic head injury approaches $25 billion per year. Could you summarize for the Committee the recommendations of that report?

Answer. The Interagency Head Injury Task Force has recommended a series of actions that represent the core of a national strategy for dealing with traumatic brain injury (TBI). The key research component of this national strategy is the creation of a national network of fifteen regional head injury research centers. The organization of a decentralized system of care networked with such centers would ensure accessibility to appropriate care for patients and concurrently the availability of a patient population for clinical trials of new therapies. Other recommended actions include the establishment of TBI as a category in reporting systems in order to have more accurate data for community planning and for the study of financial issues related to TBI. The Task Force further recommended that a Federal agency be designated to foster overall coordination and planning. The Task Force report encourages the establishment of working groups at the state and local level. The report has not yet been cleared by the Department of Health and Human Services.

STROKE

Question. Stroke is the third largest cause of death in the United States and NINDS, through 11 stroke centers throughout the country, supports basic research into stroke. People at the University of Iowa where one of these stroke centers is located, have told me about progress being made in stroke. I understand there is a continuing debate on the merits of surgery on the carotid artery. Surgery clears fat and cholesterol out of the carotid artery in the neck. It is an expensive procedure costing approximately $10,000, and whether or not the procedure actually reduces the incidence of stroke is at doubt. Dr. Goldstein, what can you tell us about the usefulness of this surgery?

Answer. The most common type of stroke is caused by obstruction of the arteries of the brain, so unclogging the arteries, in a surgical procedure called carotid endarterectomy, is often done in an effort to prevent many strokes. However, in addition to the high dollar cost of the surgery, there is also the high cost of life paid by patients who choose to have surgery and sometimes either die or have a stroke as a result of the surgery. Therefore, a decision has to be made that balances the low but definite risk of surgery with the potential benefit of preventing a

future stroke. The major problem is deciding which patients are most likely to have a significant benefit from carotid endarterectomy as compared to the benefits of medical therapy. Data currently available do not provide an adequate answer to the question. For this reason, the NINDS is supporting two large multi-center, randomized, controlled clinical trials that will provide the answers that are needed. In one trial, there are patients with previous small strokes or transient ischemic attacks. In another trial, there are patients who have no symptoms but have an artery that is nevertheless found to be partially obstructed. Both trials will take several years to complete because of the large number of patients required.

POSITRON EMISSION TOMOGRAPHY (PET) CENTERS

Question. I understand the NINDS supports nine PET centers across the country. Positron emission tomography is a sophisticated brain imaging technique which permits researchers to learn about the biochemistry of the brain without surgery or invasive procedures. I understand you are currently supporting eight such centers; how many of these centers will be supported by the FY 1990 budget?

Answer. In FY 1990, we expect to support seven PET centers at a reduced level of funding. One PET center has dropped out because the investigator moved to another grantee institution.

EDUCATION BUDGET

Question. Nutrition and lifestyle play an important part in reducing the incidence of stroke. Dr. Goldstein, I understand that you do not have any funds budgeted for an education program to help prevent stroke through better nutrition and lifestyle improvements. Why not?

Answer. Additional research is needed to develop scientific consensus on the role of nutrition and lifestyle in the etiology and prevention of stroke before an education program can be initiated. The Surgeon General's Report on Nutrition and Health states: "Although there is a wealth of scientific information supporting the relationship between diet and coronary heart disease, the link of diet to cerebrovascular disease such as stroke is less clear. However, the dietary substances that promote high blood pressure or diabetes may increase the likelihood of stroke. Of the many dietary factors that may affect blood pressure--obesity, sodium and alcohol have a role supported by scientific evidence." Healthful dietary and lifestyle recommendations relating to high blood pressure have been well-publicized by other Institutes within NIH. However, because the cerebrovascular system is physiologically different from the cardiovascular system, the effects of other dietary factors on the etiology and prevention of stroke warrant further scientific investigation.

STROKE DEATH RATES: WHITES VS BLACKS

Question. The incident rate of stroke in the white population continues to decline yet in the black population it does not decline but has stablized. Why aren't we making more progress in the black population?

Answer. We need to learn more about the causes of stroke and the methods for prevention to continue to impact on the incidence rate of scroke in all populations. The stroke rate has been declining in both black and white populations for the last several decades. The decline has been due principally to better control of high blood pressure. However, in recent years, the rate of new strokes in whites has begun to increase. We do not know if a similar increase is occurring in blacks. The reasons for this increase are not clear. We do know that the black population is more likely than the rest of the U.S. population to have strokes due to arteriosclerosis of the smaller brain arteries and more strokes for which the cause cannot be readily determined. Since blood pressure is so important as a cause of stroke, it is difficult to determine whether the different incidence rates are due to different types of stroke in the black population or due to differences in environmental factors such as salt in the diet or the extent to which high blood pressure is treated. The overall change in incidence of stroke is bringing into sharper focus the differences in stroke causes in the black population when compared to the white population. In order to study these differences in depth, community-based stroke epidemiologic projects need to be established for black populations as have been established for white populations.

DECADE OF THE BRAIN

Question. The report issued last year entitled "The Decade of the Brain" indicated that with recent medical discoveries and new sophisticated imaging technologies, we are on the verge of major breakthroughs in understanding the brain and diseases and disorders of the brain. Even with all of these scientific opportunities your budget grows only slightly faster than inflation. How much additional funding do you believe will be necessary to fully meet all of the scientific opportunities as outlined in "The Decade of the Brain report?

Answer. In our professional judgement $590,130,000 plus $26,300,000 for AIDS are required to fully meet the scientific opportunities outlined in "The Decade of the Brain" report. This is a total of $616,430,000 or $122,928,000 over the President's Budget.

FETAL NEURAL TRANSPLANTS

Question. The Department of Health and Human Services, in March 1988, imposed a moratorium on NIH-supported research that would involve the transplantation of human fetal tissue obtained from induced abortions. This action was taken in response to efforts by NIH to obtain Departmental approval to transplant fetal brain tissue into patients with Parkinson's disease. This ban did not prohibit the continuation of implantation-related projects already in progress, nor research on tissue obtained from spontaneous abortions or stillbirths. What projects, if any, were unaffected by the moratorium on fetal transplantation research?

Answer. The Institute is not supporting any projects that involve human fetal transplantation research; investigators are not submitting proposals in this research area. Research efforts unaffected by the moratorium include implantation of fetal tissue in non-human primates and in rodents. Examples of these investigations

include the study of fetal tissue in culture, the effects of growth promoting factors, and the implantation of neural tissue from fetal monkeys into adult primates with the toxin-induced model of Parkinsonism.

Question. Would you briefly describe what would be done in the proposed project involving the fetal implants into patients with Parkinson's disease.

Answer. The proposed protocol would require insertion of fetal brain tissue into a cavity, in the caudate nucleus, the part of the brain affected by the disease. The implanted tissue would be derived from sterile dissection of brain stem material obtained from an induced abortion. The Parkinson patient would be evaluated clinically and by brain imaging methods after the cavity is formed--but before any tissue is implanted--and at specified times after the tissue is implanted. This comparison would allow us to measure and evaluate any changes due to the tissue implant.

Question. What effect would a permanent prohibition of fetal tissue implantation research have on advances in areas for which your Institute has a major responsibility, including Parkinson's disease, Huntington's chorea, and spinal cord injury?

Answer. We are uncertain of the effect of a permanent prohibition on the use of fetal tissue since the relevant research is still in its early stages. A great deal of clinical and fundamental research on these disorders would not be affected by such a prohibition. On the other hand, a permanent prohibition that limits scientific inquiry would ultimately slow progress, and could influence investigators not to pursue research in these areas because they are so restrained.

Last year, the Advisory Committee to the Director, NIH, reviewed the report of the Human Fetal Tissue Transplantation Research Panel and recommended that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research using tissue from induced abortions. We are awaiting the decision of the Assistant Secretary in response to these recommendations. Fetal tissue transplantations have been performed in this country and abroad without Federal research support; the results of these efforts remain uncertain with regard to clinical benefit and require further evaluation.

We continue to seek alternative approaches to effect neuronal growth and regeneration to reverse the degenerative proceases in Parkinson's, Alzheimer's and Huntington's diseases, and in spinal cord injury.

AIDS

Question. The human immunodeficiency virus (HIV) infects the central nervous system of at least 70 percent of all AIDS victims. NINDS is actively attempting to determine how the virus damages the nervous system. What progress has been made in understanding the mode of action of HIV in the nervous system?

Answer. Significant progress has been made in understanding the clinical profile, natural history, and pathophysiology of the

effects of HIV in the nervous system, but much remains to be learned. Magnetic resonance imaging (MRI) has helped to localize specific areas of the brain which are particularly sensitive to HIV infection, particularly the basal ganglia, thalamus, and white matter. Positron emission tomography (PET) studies indicate that there is hypermetabolism of glucose in the brain areas preferentially infected with HIV-1, early in the illness. With progression of the disease, however, there is a general depression of glucose metabolism. Concurrent major pathological changes have also been found. In advanced neuro-AIDS encephalitis, infiltration by inflammatory cells has been found in the brain tissue and around blood vessels. Peripheral nerves may also be affected. How the AIDS virus causes these changes is not understood. The virus may injure the nervous tissue directly by infecting a cell to commandeer its machinery for the invader's use, or indirectly by modulating amounts and actions of neurotransmitters and nutrients. A surface component of the virus has been found to be toxic to cultured nervous tissue. Other studies suggest that the particular region of the viral surface component involved in neurotoxicity is also involved in cell fusion, thus causing destruction of the tissues. This could be responsible for the effects of neuro-AIDS on the brain.

Question. What is the status of your four planned interdisciplinary research projects to study the effect of HIV and other retroviruses on the nervous system?

Answer. We were able to fund five new neuro-AIDS interdisciplinary research centers--one more than we planned. These centers were initiated to bring together neuroscience scientists and sophisticated technology. This team approach to research on neuro-AIDS is expected to be especially productive and beneficial. The neuro-AIDS centers collect and follow cohorts of patients and are establishing epidemiological and clinical data banks. Laboratory studies focus on the analysis of patient derived information. Neurobehavioral studies in the AIDS patients are correlated with findings of more basic laboratory research. The centers are involved in the development of animal models of neuro-AIDS, studies of viral infectivity and mechanisms of nerve tissue damage, studies of opportunistic infections of the nervous system, and neurological evaluation of the effects of new treatments.

HEAD INJURY

Question. Has the Interagency Committee on Head Injury completed its assessment of the status of head injury research?

Answer. The Interagency Head Injury Task Force has completed its assessment of head injury research and incorporated its findings in a report which has been submitted to the Department of Health and Human Services for review.

Question. If so, what did the Committee identify as research needs in this area?

Answer. The Task Force focused on three research issues: the basic mechanisms of traumatic brain injury, clinical research needs, and rehabilitation needs. Research on the basic mechanisms of traumatic brain injury (TBI) includes the need to elucidate the

biomechanics of brain injury; define the molecular and cellular characteristics of primary and secondary brain injury and acute and prolonged coma; and improve experimental brain injury models. Clinical research objectives involve developing new methods and modalities for more effective diagnosis, better measurement of the degree of injury, improved post-injury monitoring and prognostic assessment; developing, modifying, and evaluating therapies; integrating clinical brain injury research into clinical care settings; and addressing informed consent issues. It stresses that rehabilitation research must use modern methods of experimental design and the need for attention to community service issues of TBI with an emphasis on progressive rehabilitation, independent living, and family participation and support.

Question. How did the Committee recommend these needs should be addressed?

Answer. In order to meet the research needs, the Interagency Head Injury Task Force recommended the establishment of a national network of regional head injury research centers. These would be affiliated with inpatient and outpatient clinical facilities to provide a focal point for clinical research. Each center would be prepared to conduct basic, clinical, behavioral, and community research. Clinical research would foster the development and evaluation of new forms of surgical and medical treatment and rehabilitative methods. In addition, it recommended an expansion of the present program of investigator-initiated research project awards.

STROKE

Question. An updated population-based study of stroke in Rochester, Minnesota indicated that the incidence rates for the period between 1980 and 1984 stopped declining. Do you have explanations for the increased frequency of stroke in Rochester?

Answer. The rate of incidence of stroke has increased in the Rochester, Minnesota, population. A similar study in Framingham, Massachusetts, reports identical results. One possible explanation is that the control of hypertension and other environmental factors reached a maximum impact sometime in the 1970s. In order to change the remaining incidence rate of stroke even more, we will have to treat additional risk factors. The challenge is to identify what these risk factors are and what treatment can be given safely to further lower the incidence of stroke. One example of research being done to help prevent strokes is a large multicenter clinical trial to see if the stroke rate can be reduced in those people who have a common heart dysrhythmia called atrial fibrillation. In this trial, two drugs, coumadin and aspirin, are being evaluated for reducing the incidence of stroke.

Question. What are the implications of this data to stroke incidence rates in the United States as a whole?

Answer. The evidence from Rochester, Minnesota, and Framingham, Massachusetts, apply to similar populations elsewhere in the United States. It has yet to be confirmed in other regions of the United States or in other types of population groups (ethnic, cultural, racial, etc.). If it exists widely, the reason may be

that current efforts to control known risk factors for stroke have had their maximum impact. We need to learn more about other risk factors and develop better treatments for known risk factors. The further significance of any leveling out in the incidence rate of stroke is that, because the population of the United States is increasing, especially the older population, different risk factors for stroke will result in changes in stroke incidence.

Question. What progress has been made in treating stroke victims?

Answer. Treatment of stroke falls into three major categories: stroke prevention, acute treatment during a stroke, and treatment after the stroke has occurred. In the category of prevention, a new drug, ticlopidine, similar in action to aspirin has been shown to be more effective than aspirin in preventing stroke in some patients at risk. Additional evidence about the importance of controlling hypertension and the cessation of smoking to reduce the risk of stroke has recently become available. In the second category, treatment of stroke as it is occurring is more difficult because of the extensive and rapid damage to the brain that occurs during a stroke. New therapeutic modalities have been identified in laboratories and more trials than ever before are underway. The possibility of much more rapid and aggressive emergency treatment for stroke has been demonstrated. Definite progress awaits the completion of several clinical trials currently planned. Finally, the NINDS has launched a pilot endeavor to develop and evaluate improved methods of restitution of function following a stroke.

Question. What are the one- and five-year rates of survival for stroke patients, and how do these rates compare with those observed 10 years ago?

Answer. The one-year survival from stroke in one population has recently been reported as 49 percent in 1970 and 62 percent in 1980. Five-year survival data for the same time period are not available. There is a report for 1960 and 1970 showing five-year survivals of 35 percent and 48 percent, respectively. Some caution has to be used in interpreting survival data because five-year survival has been increasing in general for the older population at risk of stroke.

BIOTECHNOLOGY

Question. How has biotechnology helped scientists supported by your Institute in the area of central nervous system research?

Answer. Biotechnology has greatly advanced the scope and depth of all areas of neurological and neuromuscular research, particularly neurogenetics. NINDS activities assisted by biotechnology are in two areas: (1) Basic research directly related to biotechnology, including techniques for DNA cloning, the isolation and detection of DNA, and the computer analysis of DNA and protein sequences, and (2) A broader research base, including studies in the fields of genetics, cellular and molecular biology, neuroimmunology, neurovirology, neurochemistry, and neuropharmacology.

One of the most exciting developments in basic genetic research is a technique that enables scientists to follow the inheritance pattern of specific differences in DNA sequences in families in which a genetic disease has been found, and for which neither the gene nor the biochemical defect is known. If linkage between the occurrence of an inherited illness and a specific DNA sequence (called a marker) is observed, then the general location of the gene causing the particular disorder can be identified. Eventually this will enable researchers to isolate the specific gene and determine its protein product. Markers also have the potential to expose neurogenetic diseases years before symptoms appear, opening the way for more timely therapeutic intervention. This technique has already been used successfully to identify markers associated with the genes for a number of neurological disorders, including Huntington's disease, Duchenne's muscular dystrophy, and neurofibromatosis.

Question. How soon do you predict we will have cures for disorders such as schizophrenia, Alzheimer's, and epilepsy as a result of biotechnology-related advances?

Answer. Ten years ago, we were just starting to use recombinant DNA and other advances in biotechnology. Today the neurogenetic field explodes with findings that enable scientists to predict the future expression of a genetically caused disease or reveal the location of a defective gene. While it is not possible to predict when a cure will be discovered or developed, during the next decade, gene-mapping and sequencing techniques will permit scientists to isolate and analyze specific genetic defects, and gene therapy may guide them to treatments or cures for an increasing number of neurological and neuromuscular disorders.

Using recombinant DNA technology to make DNA probes, at least one gene related to familial Alzheimer's disease has been linked to human chromosome 21. Current research is focused on isolating the gene, identifying the nature of its product, and determining how the gene and its product are involved in the brain cell and memory loss of Alzheimer's disease. Once that has been accomplished, it may be possible to develop an intervention to prevent these losses.

The tools of biotechnology are also being used to study schizophrenia. The first clear evidence of a possible genetic basis for a major psychiatric disorder was the discovery of a marker for one form of manic-depressive illness. Research using similar techniques of biotechnology may in the future be able to achieve similar successes with other psychiatric disorders, including schizophrenia.

Genetic factors involved in several different epileptic syndromes are being investigated with the techniques of biotechnology to determine whether a patient inherits a susceptibility to specific types of epilepsy or a more generalized tendency to have seizures. One epileptic syndrome known to be inherited is juvenile myoclonic epilepsy (JME). Combined clinical and basic science research, using modern molecular genetic technology, has localized the approximate chromosomal site of JME. This first characterization of an inherited seizure disorder will provide new insights into the basic mechanisms, treatment, and prevention of seizure disorders.

EFFECT OF BUDGET REDUCTIONS

Question. Are there neurological research areas of major importance which you will have to restrict because of the proposed budget?

Answer. Specific research areas that will be restricted include: support of research on head and spinal cord injury; research in the NINDS-supported Positron Emission Tomography (PET) centers; research on the genetic basis of neurological disorders; study of the increasing stroke occurrence in white and possibly in black populations; support of clinical trials on the drugs that are emerging from our Antiepileptic Drug Development Program and promising therapies for Parkinson's disease and multiple sclerosis.

HEAD INJURY

Question. Regarding the Head Injury Task Force Report, what would be the estimated costs for the research program described in the report?

Answer. The report does not include specific cost estimates for the recommendations. However, the establishment of fifteen regional research centers (five per year for each of three years) would require an increment of $10 million per year for each of the three years. Additional costs of $5 million each year for three years is also needed for individual research project grants to support investigator-initiated projects.

STROKE IN THE BLACK POPULATION

Question. With all the good efforts that the NINDS and NHLBI have addressed at the problem of stroke, why is stroke still high in the Black population?

Answer. For a long time, the stroke rate has been declining in both black and white populations, although the incidence rate in blacks continues to be higher than in whites. However, in recent years, the rate of decline has slowed in blacks when compared with whites. More frequent and more severe hypertension that is resistant to treatment may be part of the explanation for a higher incidence of stroke in the black population. In addition, the incidence of the various types of stroke are different in the black population when compared to whites. One type of stroke which occurs regularly in the black population and more rarely in the white population (occlusions within the system of small vessels that penetrate deep within the brain) is more difficult to prevent with current treatment strategies.

DECADE OF THE BRAIN

Question. Last year this Committee received a report from the NINDS Council on the "Decade of the Brain". Tell us why this should be the Decade of the Brain.

Answer. With the support of the Congress over the last several years, the tools and the knowledge base have been developed that--if fully utilized--hold the potential for major progress across the

spectrum of neurological and neuromuscular diseases that afflict millions of Americans.

For instance, the long-term investment in muscular dystrophy research is paying off with the discovery of the gene responsible for Duchenne's and Becker's muscular dystrophies. With this knowledge, we can move on and find out more about how the products of this gene affect muscles and translate that information into significant benefit for the patients. The technologies developed for this research can be used to help the many other children and adults who suffer from other genetic neurological and neuromuscular disorders such as Huntington's disease, Gaucher's disease, and neurofibromatosis.

Head and spinal cord injuries affect many hundreds of thousands of people each year, leaving many of them brain-damaged or paralyzed. Previously, it was thought that little could be done for a patient with such injuries. We now have substantial evidence that if the patient's brain or spinal cord can be protected within 4 hours of damage, permanent damage can be prevented in many cases. Further, there is evidence that although nerve cells do not normally regrow after being damaged, they do have the potential for growth; we must find out how to turn on and control this growth.

Results from research on neural prostheses to restore muscle movement and sensory perception are also full of promise. Greater effort is needed to develop the hardware, such as the electrodes, that will make all this a reality.

Many neuroscience advances are due to the modern brain imaging techniques of magnetic resonance imaging (MRI), magnetoencephalography (MEG), and positron emission tomography (PET). These techniques are used to study a large number of neurological diseases--brain tumors, epilepsy, Parkinson's disease, schizophrenia, Alzheimer's disease, Huntington's disease, and Tourette's syndrome--to find clues to the source of the diseases and evaluate the effectiveness of medications without physically entering the brain. Investigators are increasingly using PET to also study "higher cognitive functions" such as learning, thinking, and memory; drug addiction; and the nerve cell receptors critical for brain activity.

For the hundreds of thousands of Americans afflicted by stroke each year, additional risk factors--especially those in which intervention may be possible--must be identified in order to continue the advances already occurring in stroke prevention.

We have made great progress in understanding the role of viruses in several neurological diseases. More remains to be learned to clarify the possible role of viruses in multiple sclerosis, the role of the human immunodeficiency virus plays in causing the neurological effects of AIDS, and the effects of the broad class of retroviruses on nervous system disorders such as tropical spastic paraparesis ("tropical multiple sclerosis"). These areas of research offer exciting promise of uncovering the possible causes of other deadly and mysterious disorders of the brain.

We also know much more about neurotransmitters--the messengers by which nerve cells communicate with each other--and the sodium

channels that regulate nerve cell activity. But, more research is needed before we can apply this knowledge to treatment of memory disorders, Parkinson's disease, head injury, and numerous other neurological disorders.

These are just a few examples of the exciting gains made in all facets of neurological research. The momentum in the neurosciences is at a critical point. We now have the tools such as PET and MRI, and advances from basic and clinical neuroscience research to move ahead to a new level of research effort and achieve significant clinical progress in the treatment and prevention of neurological and neuromuscular diseases, and even greater basic understanding of how the brain and nervous system function. The state of the science justifies a higher level of effort and to make the coming decade, the "Decade of the Brain."

NEUROGENETICS RESEARCH

Question. In the past few years, scientists have made significant progress discovering genes or markers for many neurological diseases. What is the status of neurogenetics research and what are its future directions?

Answer. Research in neurogenetics continues to be very active. Genes for some 50 neurological diseases have been localized to specific chromosomes. The specific genes responsible for the common Duchenne's and Becker's types of muscular dystrophy have recently been identified. Future research directions include continued search both for the genes responsible for other neurological diseases for which only chromosomal markers are currently available, such as Huntington's disease and the two forms of neurofibromatosis, and for diagnostic markers for additional neurogenetic disorders. New and more reliable presymptomatic tests will become available for more diseases and more at-risk individuals. New therapeutic avenues will also be opened, such as gene replacement or modification and gene product replacement, as genes and their products are identified and characterized.

AIDS

Question. The effects of AIDS on the brain and the nervous system have emerged as a major problem for many AIDS patients, particularly children with AIDS. What type of research studies are needed to address this problem?

Answer. Clinical and laboratory studies of children, especially child-mother pairs are of great importance. The majority of cases of pediatric AIDS are due to perinatal infection passed to the baby from a HIV infected mother, resulting in delays in brain development and in cerebral atrophy. Additional studies that address the route and mode of HIV transmission from the mother into the fetal brain are needed. Studies of pathogenesis of brain dysfunction in the developing nervous system are essential to understanding of the course and prognosis of the disease in children.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

MULTIPLE SCLEROSIS

Question. Please describe for the Committee the research efforts on Multiple Sclerosis (MS) supported by the NINDS in FY 1989 and that you plan to support in FY 1990.

Answer. A broad array of basic and clinical research in multiple sclerosis (MS) is supported by NINDS in FY 1989, including several viral and immunopathologic animal models of the disease, studies of myelin metabolism, studies of the etiology and epidemiology of MS, studies of immunological abnormalities in MS patients, and efforts toward therapeutic modulation of the immune system that provide the bases for new treatments.

We expect that the major research thrusts will follow the same lines in FY 1990. Clinical trials of new treatment modalities could also be undertaken. The nature and specificity of the cellular and humoral immune abnormalities will be studied, specifically the importance of chemical components of myelin in the development of autoimmune disease. The search for an "MS virus" will continue based upon new technology. Studies of viral, immune, and genetic animal models of MS will continue in the context of new immunological, molecular, and biological concepts and techniques.

Question. How much do you estimate will be spent on MS research in FY 1989 and FY 1990?

Answer. The estimated support for MS and MS-related research is $50,374,000 in 1989 and $52,396,000 in 1990.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS

STATEMENT OF DR. JAY MOSKOWITZ, ACTING DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next is the National Institute on Deafness and Other Communication Disorders, and Dr. Moskowitz.

Dr. MOSKOWITZ. Thank you, sir.

It is a privilege and a pleasure to appear before this committee as the Acting Director of the newly created National Institute on Deafness and Other Communication Disorders, and to serve on behalf of the 30 million Americans who suffer from hearing, balance, speech, language, smell, taste, and other communication disorders.

At the outset, I would like to thank you, Mr. Chairman, for all the Americans who suffer from the silent handicaps within the mission of the Institute, as well as those in the deaf cultural community for your support in the Institute's establishment.

Since October 1988, we have made much progress. We have initiated a nationwide search for a permanent director. We have considered and submitted to the Secretary nominations for membership of the newly chartered Advisory Board and Advisory Council. We have identified programs in deafness and other communication disorders totaling a comparable figure of approximately $94.8 million for transfer from the National Institute of Neurological Disorders and Stroke.

In addition, a Task Force for the Development of a National Research Strategy for Deafness and Other Communication Disorders, composed of 11 panels of experts, was convened to assist the NIDCD in preparing a plan to initiate, expand, intensify, and coordinate the activities of the Institute respecting disorders of hearing, balance, voice, speech, language, taste, and smell.

The plan describes the state of the knowledge in the major areas of research within the purview of the new Institute, identifies emerging research opportunities, and suggests over 300 approaches to meeting current and projected needs.

Time permits me to describe just one of the most recent research accomplishments that will serve as the foundation for the activities under this new Institute.

The production of sensory cells in the ears of birds and mammals was thought to cease well before the time of birth, therefore, it was assumed that any subsequent loss of auditory and vestibular hair cells in birds and mammals, as a result of disease, drug therapy, loud noise, or aging, would permanently damage the sense of hearing and balance.

Recently, however, two teams of scientists have shown that auditory hair cells in the mature inner ears of fowl regenerate after acoustic trauma, and they have demonstrated that functional recovery has occurred, as indicated by the restoration of normal levels of electrophysiological activity in the auditory nerve of chickens.

These studies offer new hope for hair cell regeneration in mammals and great potential for some deaf individuals.

Mr. Chairman, the training portfolio of the new Institute provides a framework upon which new and intensified attacks on deafness and other communication disorders can be mounted.

This area will, however, receive special emphasis in the coming years.

To quote from that task force: "Many of the new Institute's programs are now sustained only by tiny groups of active investigators. These groups are threatened with extinction as the present leadership approaches retirement. Enormously productive, contemporary scientific disciplines, including genetics, immunology, cell and molecular biology, biochemistry, and epidemiology are seriously underrepresented in many of the NIDCD's research programs.

Thus, one of the first priorities of this new Institute will be to address the critical shortage of research personnel and training support.

In conclusion, there have been some exciting developments within the scientific programs of the Institute. Our National Advisory Board, which will meet next month, will assist us in the process of establishing the next research priorities. With the increased opportunities for research and invigorating training programs, we will witness an exciting rejuvenation of research in hearing and communication sciences that will benefit millions of Americans.

PREPARED STATEMENT

Mr. Chairman, the fiscal year 1990 budget for NIDCD is $99.9 million.

I would be pleased to answer any questions you may have.

[The statement follows:]

STATEMENT OF DR. JAY MOSKOWITZ

It is a privilege and a pleasure to appear before this Committee as Acting Director of the newly created National Institute on Deafness and Other Communication Disorders (NIDCD) and to serve on behalf of the 30 million Americans who suffer from hearing, balance, speech, language and other communication disorders.

Since October of 1988, we have initiated a nationwide search for a permanent Director, considered nominations for membership of the newly chartered Advisory Board, and identified programs in deafness and other communication disorders totaling $91,677,000 for transfer from the National Institute of Neurological and Communicative Disorders and Stroke to the NIDCD. These funds will support ongoing research project grants, research and development contracts and intramural research projects, and new and competing renewal projects.

In addition, a Task Force for the Development of a National Research Strategy for Deafness and Other Communication Disorders, composed of ten panels of experts, was convened to assist the NIDCD in preparing a plan "to initiate, expand, intensify, and coordinate the activities of the Institute respecting disorders of hearing, balance, voice, speech and language, taste, and smell." The recommended strategy describes the state of knowledge in the major areas of research within the purview of the new Institute, identifies emerging research opportunities, and suggests approaches to meeting current and projected needs.

I would like to describe a few of the most recent accomplishments in some areas of research that will serve as a foundation for activities under the new Institute.

Research results indicate that excitatory amino acids are major neurotransmitters in the mammalian central nervous system and may also be involved in neuronal degeneration under conditions of ischemia and in some diseases. Several studies have identified these amino acids as neurotransmitters at a number of synapses in the auditory system. Investigators have recently isolated and made monoclonal and polyclonal antibodies to a "kainic acid receptor." This first purification of an excitatory amino acid receptor should enable investigators to determine the function of these receptors in the auditory system. An understanding of their role might permit the use of drugs affecting these neurotransmitters in the treatment of auditory system disorders.

Because the production of sensory (hair) cells in the ears of birds and mammals was thought to cease well before the time of birth, it has been assumed that any subsequent loss of auditory and vestibular hair cells in birds and mammals as a result of disease, drug therapy, loud noise, or aging would permanently damage the senses of hearing and balance. It is now known that auditory hair cell regeneration can occur in birds after acoustic trauma and that a corresponding recovery of hearing occurs. Recently, two teams of scientists have shown that auditory hair cells in the mature inner ears of young chickens and adult quail regenerate after acoustic trauma, and they have demonstrated that functional recovery

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occurred, as indicated by restoration of normal levels of electrophysiological activity in the auditory nerve of the chickens. These studies offer new hope of hair cell regeneration in mammals.

Since the development of cochlear implants in the sixties, more than 3,000 children and adults have been implanted with a variety of these devices. Controversy continues on several issues, however, including determination of appropriate candidates, selection of a single or multichannel device, suitable preimplantation and post- implantation assessments, and rehabilitation procedures. In order to address these and other associated issues, an NIH Consensus conference was held in the spring of 1988. The conference concluded that the implant is a valuable adjunct in the amelioration of profound deafness and that there is some evidence that multichannel devices are better than single channel devices in adults. In some persons there is substantial improvement in speech recognition after implantation, although--more typically--lip reading improves.

Studies of muscle actions during respiration, swallowing, phonation, and speech are providing new data of utmost importance for understanding the basis of a voice disorder called spasmodic dysphonia. These data are now being used to design a biomechanical computerized model of normal and disordered human laryngeal function that will provide the basis for understanding and treating various speech or voice disorders. Investigators have been successful in developing a new treatment. In two studies, injection of the laryngeal muscles with botulinum toxin was successful in eliminating or dramatically reducing symptoms in over 40 patients with spasmodic dysphonia. Other trials have demonstrated that this treatment can be used in other vocal tract muscles to reduce symptoms in stuttering.

Stuttering usually occurs during the preschool years. As many as 50 to 75 percent of those who begin to stutter will become fluent by adolescence. The cause of this debilitating speech disorder and the explanation of the common spontaneous recovery have remained elusive to researchers.

Normally, the muscles involved in opening and closing the vocal cords during breathing and producing speech sounds work together smoothly and efficiently. However, investigators have found that in stutterers these muscles, particularly those in the larynx, move irregularly. Stutterers have difficulty controlling and coordinating the rapid sequential movements necessary for smooth speech production, and even their tongue and jaw movements are significantly different from those of normal speakers. These findings suggest there is an underlying neuromotor control problem in stuttering. This may have important implications for treatment and for dismissing at least one theory, long unproven yet still espoused, that favors an emotional basis for the disorders.

Most languages are linked to the auditory modality for transmission and are learned through hearing during an infant's early development of communication. Language, however, is not limited to speech and hearing for transmission. As described by Howard Poizner, Edward Klima and Ursla Bellugi in What the Hands Reveal About the Brain, systems of symbolic communication are

passed down from one generation of deaf people to the next, and have become autonomous languages not derived from spoken languages. These "visual-gestural languages of the deaf" are rooted in the visual modality and provide a means for examining competing explanations of how the brain is organized for language and how that organization can be modified. Studies on the breakdown of sign language following localized brain damage in deaf signers have provided important implications of brain organization for sign language. The study of sign language breakdown now offers hope of discovering the basic principles underlying both the specialization of the two cerebral hemispheres and the modification of their functions.

Olfactory receptor neurons have been shown to provide a direct connection between the external environment and the brain. A vigorous transport system moves substances taken up by the cell bodies located in the nasal cavity and takes them along the olfactory nerve into the olfactory bulb, and in some cases, from the bulb into other parts of the central nervous system. A variety of low-molecular-weight organic chemicals, some proteins, colloidal gold, and pathogens apparently reach the brain via this route, which could enable the administration of therapeutic substances to specific targets in the brain, bypassing the blood-brain barrier that ordinarily prevents such access. It is also a pathway for some toxins and pathogens. For instance, via this path, herpes simplex virus type I, some neurotropic arboviruses, and vesicular stomatitis virus are transported into the brain, where they can spread extensively. According to some studies, the olfactory sensory deficits expressed in early stages of Alzheimer's disease may be the result of a causative vector that gained entry through these receptor neurons.

Balance disorders are extremely common, especially in elderly persons and in those who travel in space. A majority of individuals over 70 years of age report problems of dizziness and imbalance, and balance-related falls account for more than one-half of the accidental deaths in the elderly. The maintenance of balance is a complex process. Because the balance mechanism of the inner ear interacts with all the major sensory and motor systems in the brain, balance control is vulnerable to a large number of disease processes. New assessment techniques employing computer technology, including rotatory testing and posturography, are now available to the clinician to evaluate the role of each of the major subsystems in balance disorders. These studies are contributing to a growing understanding of the adaptive and compensatory mechanisms employed by the central nervous system in the restoration of normal function following injury to the inner ear. This understanding is proving invaluable in the development of rehabilitative strategies for balance-disordered patients.

The research and training portfolio of the NIDCD provides a foundation upon which a new and intensified attack on deafness and other communication disorders can be mounted.

Mr. Chairman, the FY 1990 budget request for NIDCD is $99.9 million.

I will be pleased to answer any questions you might have.

BIOGRAPHY OF DR. JAY MOSKOWITZ

January 9, 1943, New York, New York
Married, two children

Education: B.S., Queens College, 1964
Ph.D., Brown University, 1969

Professional History: 1964-65, Lecturer in Biology, Queens College. 1966-67, Graduate Teaching Assistant; 1967-69, Predoctoral Fellow, Division of Biological and Medical Sciences, Brown University. 1969-71, Lt. Cmdr., U S. Public Health Service; and Postdoctoral Research Associate, Pharmacology-Toxicology Program, National Institute of General Medical Sciences, NIH. 1971-72, grants Associate, Division of Grants, NIH. 1972-73, Program Coordinator, Division of Lung Diseases (DLD), National Heart and Lung Institute (NHLI), NIH. 1973-74, Program Coordinator and Acting Chief, Special Programs and Resources Branch, DLD, NHLI, NIH. 1976-81, Associate Director for Program Planning and Evaluation and Director, Office of Program Planning and Evaluation, Office of the Director, National Heart, Lung, and Blood Institute (NHLBI), NIH. 1981-86, Associate Director for Scientific Program Operation, NHLBI, NIH. 1986-1987, Associate Director for Program Planning and Evaluation, Office of the Director, NIH. 1988-present, Associate Director for Science Policy and Legislation, Office of the Director, NIH. Appointed October 31, 1988 as Acting Director of the National Institute on Deafness and Other Communication Disorders.

Professional Organizations: Society for Experimental Biology and Medicine, American Association for the Advancement of Sciences, The Society of the Sigma Xi (full member).

Honors, Awards: New York State Incentive Scholarship, 1960-64, U.S. Public Health Service Predoctoral Traineeship, 1965-66. University Fellow. John G. Peterson Scholarship, Brown University, 1968-69. William A. Jump Memorial Foundation Meritorious Award 1977. Equal Employment Opportunity Award, 1977. NIH Director's Award 1978. U.S. Public Health Service Superior Service Award, 1980. Senior Executive Service Performance Award, 1981, 1983, 1984, 1985, 1986, and 1987.

Senator HARKIN. Thank you.

I was reading that information about the birds, the chickens, the quails. Whatever prompted people to look at those species in the beginning? Why not something else?

Dr. MOSKOWITZ. It's because of the easy accessibility to the hair cells and auditory nerve and the simplicity of their brain. There are certain animal models that we have that we can use in hearing science. The chinchilla, has a large cochlea, and is used to study otitis media because of the size of the middle ear and cochlea.

We pick our species as animal models which have endowment of certain areas, and the hair cells, the auditory nerve, or the cochlea would be examples.

Senator HARKIN. Is it true or just an old wives tale that as dogs get older they do not lose their hearing, that once a dog is a puppy, its hearing remains the same, regardless of how old the dog gets?

Dr. MOSKOWITZ. I am not an expert on folklore. I don't know that.

Senator HARKIN. I have been told that ever since I was a little kid, that no matter how old a dog is, he can always hear you.

OK. It is $99.9 million, which is for continuation of activities previously conducted by the Neurology Institute. I understand it does not include any of the new initiatives authorized in the legislation.

The legislation authorized new multipurpose centers that would conduct basic research, do clinical work, train physicians, as well as conduct educational programs for the general public.

Does any of your budget request of $99.9 million contemplate the funding of any of these new centers?

Dr. MOSKOWITZ. No, sir.

Under this budget, we will be able to do the planning for these new activities and start getting groups together to review how these will take place. But we have no budgeted dollars for these activities.

Senator HARKIN. The new legislation authorizes an investigation into several so-called silent disorders, including those affecting hearing, balance, voice, speech, smell.

Does your budget request of $99.9 million include funding for the newly authorized responsibilities of voice, speech, language, taste, and smell?

Dr. MOSKOWITZ. We would just be able to continue the programs that we have in those areas under this budget.

Senator HARKIN. It has been said that research into the ear and throat is at least two decades behind research into diseases affecting the other organs. In fact, there are approximately 50 trained physician researchers who specialize in the problems of the ear and throat.

Does that correspond with what you know?

Dr. MOSKOWITZ. That is correct, sir.

Senator HARKIN. There is a need to attract individuals with a background in molecular biology, biochemistry, and genetics to study the underlying dysfunction associated with the several diseases.

Again, do you feel that your revised 1990 budget puts an adequate emphasis on training in this area? What does it do in that area?

Dr. MOSKOWITZ. The revised budget will just continue the present program as it exists. We are presently calling together a group of training mentors from NIH-supported organizations, as well as those who are supporting just clinical medicine, to find out how we can recruit more individuals. As you say, 50 research trained otolaryngologists is not even one for each of the 100 or more medical schools in the country. We are trying to develop methodologies and programs to recruit more people into this field.

Senator HARKIN. Well, of course, we have talked about this in the past, but it always seems strange to me that the one thing that affects almost every human being is that we all lose our hearing as we get older. We lose parts of it. We lose our ability to hear some things. And yet, we just have not really done much in this area.

What is your professional judgment budget?

Dr. MOSKOWITZ. My professional judgment budget for this Institute is $131.5 million.

Senator HARKIN. That's $131.5 million. If you got that, could it be well spent? Could you do high quality research with money like that?

Dr. MOSKOWITZ. Yes; this is a very conservative professional judgment. We feel that we could spend all of these dollars.

Senator HARKIN. I'm sorry, but did you say yes.

Dr. MOSKOWITZ. Yes.

Senator HARKIN. You said it was a conservative professional judgment budget.

Dr. MOSKOWITZ. Yes.

Senator HARKIN. That's about all of the questions that I have.

Dr. Moskowitz, do you have anything else that you want to bring to my attention?

Dr. MOSKOWITZ. No, except that just once again, we would like to thank you for your support in the establishment of this Institute.

Senator HARKIN. I still want to continue that.

Again, the increase from last year is only about $5.1 million. That is what percent?

Dr. MOSKOWITZ. It's 5.4 percent.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you. I knew it was approximately 5 percent. It is 5.4 percent.

We will have some additional questions which we will submit to you for your response.

[The following question was not asked at the hearing, but was submitted to the Institute for response subsequent to the hearing:]

QUESTION SUBMITTED BY THE SUBCOMMITTEE

DATA SYSTEM AND INFORMATION CLEARINGHOUSE

Question. Authorization legislation requires the establishment of a National Deafness and Other Communication Disorders data system for the collection, storage, analysis, retrieval, and dissemination of data derived from patient populations with disorders of hearing and communication processes.

Does your revised 1990 budget have adequate funds in it to establish the information clearinghouse?

Answer. No additional funds have been included in the revised budget for fiscal year 1990 to administer the data base or the clearinghouse. We have begun a feasibility study to identify existing resources and needs of both scientific and public communities. This study is our primary step in beginning a pilot program.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next we will go to the National Institute of General Medical Sciences and Dr. Ruth Kirschstein.

Dr. KIRSCHSTEIN. Senator Harkin, I am very pleased and privileged to report to you on the basic biomedical research and research training activities of the National Institute of General Medical Sciences.

NIGMS plays a crucial role in the development of the fundamental knowledge which can lead to a basic understanding at the cellular, subcellular, and genetic levels of those diseases that my colleagues at the table have been telling you about, and that those Institute directors who testify this afternoon, will also tell you about.

In fiscal year 1990, over 40 percent of the proposed NIGMS budget will be allocated to research designated to provide an in-depth understanding of the precise structure and function of mankind's estimated 100,000 genes. It is errors in the chemical and physical makeup of one or more of these genes, or even in their expression, that appear to account for the 4,000 or more inherited human diseases that afflict mankind.

Exciting developments in genetics research are coming so rapidly that it is hard to keep track of them. Just recently, a new discovery by Dr. David Ward at Yale University has developed into a spectacular technique, which has vastly improved the speed with which scientists can determine the physical location of genes and genetic markers on particular chromosomes. Using this method, Dr. Ward has been able to confirm the fact that the Huntington's disease gene can be pinpointed to the very tip of the short arm of chromosome 4.

Research in this area has been lagging recently because there has been some disappointment that, after the discovery, several years ago that the gene was somewhere on the short arm of chromosome 4, it could not be located in precise detail. Dr. Ward's discovery has sparked renewed enthusiasm that the puzzle of Huntington's disease can be solved.

But, in order to fully understand human biology, we must also understand the functioning of the cell and of its many parts. There was a recent five part series in The Washington Post which showed that we are obtaining an understanding of how cells and their constituent molecules not only function to accomplish many of the life-sustaining tasks, but also, just as importantly, how they malfunction, leading to various human disorders.

I have provided a reprint of this Washington Post series of articles for members of the committee.

Senator HARKIN. I would like to see that.

Dr. KIRSCHSTEIN. I have provided reprints to the staff.

Senator HARKIN. Thank you.

Dr. KIRSCHSTEIN. The pictures that are in this reprint are really very beautiful reproductions. Unfortunately, the Post articles, printed on newsprint, did not do justice to these photographs, many of which came from researchers supported by the National Institute of General Medical Sciences.

In addition, the Institute supports a great deal of research in chemistry. This is very important because the chemical basis of disease is going to be, and is continuing to be, of great significance.

But, while the potential payoffs from this array of fundamental research are very great, they are necessarily dependent on the availability of large numbers of creative, dedicated, and well-trained investigators. NIGMS is the Institute that supports the preponderant number of individuals in research training.

We support a number of research training programs, among them, the Biotechnology Research Training Program, new in fiscal year 1989, to be funded with $2.8 million provided by the Congress. This is a program which is designed to ameliorate the growing shortage of researchers who can apply the skills of mathematics, engineering, computer sciences, chemistry, and physics to biological research problems in both the biotechnology industry and at universities. This program will support research training grants, as well as individual post-doctoral fellowships, the Lawton Chiles Fellowships.

PREPARED STATEMENT

The NIGMS Medical Scientist Training Program provides support for individuals to seek the combined MD/Ph.D degree, and represents one of the Institute's major success stories. Its graduates play leading roles in the research activities of all of the NIH institutes.

Mr. Chairman, the fiscal year 1990 budget request for the basic research and research training programs of NIGMS is $766,421,000.

I would be very pleased to answer questions.

[The statement follows:]

STATEMENT OF DR. RUTH L. KIRSCHSTEIN

In this, my fifteenth year, I am proud to report, once more, on the essentiality of the basic biomedical research and research training activities of the National Institute of General Medical Sciences (NIGMS). Despite the enormous expansion of the knowledge base that has occurred in these 15 years, people still do suffer and die each day because we still continue to lack an understanding of many of the fundamental biological abnormalities that lead to a host of diseases. We cannot yet diagnose and treat many such disorders. The NIGMS plays a crucial role in the development of the knowledge which can lead to a basic understanding of these diseases at the cellular, subcellular, and genetic levels.

In FY 1990, over 40 percent of the proposed NIGMS budget will be allocated to research designed to provide an in-depth understanding of the precise structure and function of mankind's estimated 100,000 genes. Errors in the chemical or physical makeup of one or more of these genes, or in their expression, appear to account for the 4000 or more inherited human diseases, many of which--like Huntington's disease--rob their victims not only of their lives, but of their human dignity as well.

Research in the field of genetics has been expanded in the past two years by the addition of studies directly related to the Human Genome Research initiative. As we discussed last year, this initiative represents a special effort to identify the precise chromosomal location of each and every one of the human genes as well as those of a number of other important model organisms. In addition, as part of the long-range genome project, scientists will determine the order or sequence of the 3 billion nucleic acid subunits that are the chemical building blocks of the total genome. This knowledge, along with the equally important progress being made in all other areas of genetics, will lead to a better understanding both of normal life processes and of the underlying causes of many disorders.

One of the most exciting developments in genetics research supported by NIGMS just occurred in the last several months. Dr. David Ward at Yale University has developed a spectacular new technique which has vastly improved the speed at which scientists can determine the physical locations of genes and genetic markers on particular chromosomes. Using this promising method, called confocal microscopy, along with laser beam scanning of entire chromosomes stained with fluorescent dyes, a method he previously developed, Dr. Ward and his colleagues, in a few short weeks, have visualized a series of genetic markers along chromosome 11. This enabled them to determine the correct order of the markers, an accomplishment that otherwise would have taken many months. Dr. Ward and his colleagues have also used confocal microscopy to study the location of the gene responsible for Huntington's disease. As you know, a marker for this disease was discovered a number of years ago, but further progress has been very slow. Dr. Ward's remarkable new method has confirmed that the Huntington's disease gene can be pinpointed to the very tip of the short arm of chromosome 4, and has sparked renewed enthusiasm that the puzzle of this disease may soon be solved.

In another exciting advance in genetics research, grantees at the Universities of Utah and North Carolina have greatly improved the efficiency of introducing genes (pieces of DNA) into specific sites

on the chromosome. In the model systems used, these "foreign" genes behaved properly and coded for normal proteins. These successful gene transfer studies are leading us closer and closer to the ability to replace defective genes with healthy ones, to provide so-called gene therapy.

However, for a full understanding of human biology, we must also understand the functioning of the cell and of its many parts. A recent five-part series in The Washington Post, noted that "Cancer and the common cold, heart disease, and hay fever, even AIDS and arthritis--all afflict people because of failed mechanisms within cells. This is why biologists say basic research--aimed at understanding how cells work rather than at conquering any given disease--promises knowledge that can be used to attack many, if not all, diseases."

The NIGMS Cellular and Molecular Basis of Disease (CMBD) Program is aimed at obtaining such an understanding of how cells, and their constituent molecules, function to accomplish not only many life-sustaining tasks, but, just as importantly, how they malfunction, leading to various human disorders.

It has been known, for many years, that environmental stresses, such as a severe temperature elevation, cause cells to profoundly change their pattern of protein synthesis. Production of most cellular proteins ceases, but the rate of synthesis of others, the so-called heat shock proteins, markedly increases. By studying model cellular systems, scientists at the Rockefeller University, the University of California and Princeton University have shown the importance of these heat shock proteins in the protection of the body's cells from various stresses. What they have recently shown is that the heat shock proteins also serve, in the face of such stresses or any other danger, to brace the internal cellular structures against disintegration. In this way, the cells can survive until normal function can be restored. Of great importance is the most recent finding that heat shock proteins are produced rapidly in areas of the body that undergo severe trauma or burn injury and also appear to circumscribe the damage and protect the undamaged cells until the healing process can begin. This is a vivid illustration of the importance of fundamental studies of cell biology to the most practical aspects of human dysfunction. Other grantees are exploring important areas related to the transport of proteins, into and out of cells, as well as within the cells themselves; the action of enzymes and antibodies in aiding in the response to cellular insults and the detailed structures and functions of various cellular constituents.

One of the most interesting recent discoveries made by a grantee of the Institute's Pharmacological Sciences Program actually derives from a phenomenon uncovered over 5,000 years ago. Practitioners of Chinese herbal medicine for many, many years, have been using extracts made from the leaves of the gingko tree to treat a variety of ailments. This tree, originally from China, now grows throughout the United States and is, indeed, "The Tree that Grows in Brooklyn." Modern day scientists have shown that such herbal therapy is scientifically sound. Preliminary evidence indicates that one of these extracts, referred to as gingkolide B, is highly effective in increasing the survival of transplanted hearts in rats, in treating asthma and other allergic, inflammatory disorders and in inhibiting a factor which prevents the formation of blood clots.

Until this past year, full scale studies of the mechanism of action of gingkolide B were hampered by the lack of large quantities of this substance in purified form. Recently, an NIGMS grantee at Harvard University has successfully developed a method to synthesize pure gingkolide B in the laboratory. Now, a series of studies have been started involving rigorous tests of a number of experimental drugs containing gingkolide B. These tests are designed to determine its effectiveness in treating a wide range of medical problems. It is likely that the methods used to synthesize this substance are easily adaptable to the production of related chemicals which may also have therapeutic potential.

Other grantees of the Pharmacological Sciences Program are also performing studies designed to expand the work of long-time Institute grantee, Dr. Donald Cram, who won the Nobel Prize in 1987 for developing an approach to making "mimics" of either the active site of an enzyme or of that portion of a cell receptor responsible for binding to so-called "signal carriers." Using the technology developed by Dr. Cram, during the past year, an NIGMS grantee has synthesized a new compound that is expected to enhance the delivery of certain types of anti-cancer drugs to tumors that previously have been extremely hard to reach.

Grantees of the Biophysics and Physiological Sciences Program are using the techniques of X-ray crystallography and nuclear magnetic resonance (NMR) spectroscopy to examine the detailed structure and shape of both proteins and nucleic acids. Because these shapes change over time, such studies are likely to shed light on fundamental aspects of normal life processes as well as many disease states.

One grantee at the Massachusetts Institute of Technology is using X-ray crystallography, at low temperatures to study specific chemical mechanisms that allow proteins to assume various shapes. Ordinarily, when crystals are cooled, they break up. Dr. Gregory Petsko has developed new techniques to prevent the breakage of crystals in the cold, allowing him to determine what changes in protein structure occur at low temperatures. This has provided significant new information about how the shapes of proteins vary in response to different environments.

Other NIGMS grantees at Cornell University have developed techniques to take photographs of the X-ray diffraction of molecules one million times more rapidly than was previously possible. Up to now, diffraction studies have required long exposure times and have provided only a static view of a molecule. This new technology opens the way for studies of how molecules change their shapes as they perform their biological functions.

The studies of the structure of the AIDS virus proteins, being done by NIGMS grantees, are going very well. Crystals of several viral proteins have been obtained and information related to the definitive relationships of these proteins to their functions is being sought. It is anticipated that, these studies will lead to the development of chemicals, designed specifically to inhibit the active proteins of the AIDS virus by fitting into crevices in the molecule. Prospects for the discovery of anti-viral drugs, based on the structural biology of this virus, are excellent.

While the potential payoffs from this array of fundamental research supported by NIGMS are very great, they are necessarily dependent upon the availability of large numbers of creative, dedicated and well-trained investigators. For this reason, NIGMS supports a number of research training programs, aimed at producing future scientists. In FY 1990, an estimated 3,380 trainees will be supported, most of whom will need about 10 years of study before they become independent researchers.

Several of the Institute's training program are unique and make important special contributions to future research manpower needs in the biomedical sciences. These include:

- Molecular Biophysics - Such research training in fields related to structural biology is of great importance to the efforts to combat AIDS. The NIGMS has assumed the primary responsibility at NIH for such AIDS-related research training.
- Biotechnology Training - The NIGMS is currently in the process of reviewing applications for a new biotechnology research training program to be supported by $2.8 million provided by the Congress for this purpose in FY 1989. This program is designed to ameliorate the growing shortage of researchers who can apply the skills of mathematics, engineering, computer science, chemistry, and physics to biological research problems both in universities and in the biotechnology industry. The President's budget provides for steady state support for this newly begun research training effort in FY 1990.
- The Medical Scientist Training Program provides support for individuals seeking the combined M.D.-Ph.D. degree. This program, designed to address a continuing shortage of researchers with clinical training, represents one of the Institute's major success stories, since its graduates play leading roles in the research activities of all of the NIH institutes. In its 1986 report on AIDS, the National Academy of Sciences pointed to this program as the first place to look for new scientific talent in the "war on AIDS."
- The Minority Access to Research Careers (MARC) Program has been equally successful in preparing students at institutions with large minority enrollments for biomedical research careers. This program is assuming increasing importance, as persons from minority groups come to represent a larger and larger proportion of the pool from which future scientists must be drawn. The success of the MARC Program has recently prompted the National Science Foundation, and the Sloan Foundation in New York to restructure their minority-oriented research training programs along the lines of the "MARC Program Model." Such actions were recommended by the 1988 report of the U.S. Task Force on Minorities, Women, and the Handicapped in Science and Technology, "Changing America."

Mr. Chairman, the FY 1990 budget request for the basic research and research training programs of NIGMS is $766,421,000. I would be pleased to respond to any questions you might have.

BIOTECHNOLOGY RESEARCH TRAINING PROGRAM

Senator HARKIN. Last year, your Institute assembled a panel of university, industry, and Government scientists to analyze the needs of the biotech industry.

The consensus of this panel was that there was a need for a significant increase in biotechnology research training programs, with goals established to increase the national pool of trainees and fellows to 1,500 a year, and working toward that goal by adding training candidates at the rate of 250 per year.

The biotechnology industry is projected to be a $20 billion industry within 10 years. For the United States to remain competitive in this field, it is important to encourage and assist American industry.

Why hasn't the Institute requested the next increment of training slots for this initiative? How many training slots have you requested?

Dr. KIRSCHSTEIN. The funding level for fiscal year 1989 is $2.8 million, which will support 130 trainees. The $2.9 million provided in the President's budget for fiscal year 1990 will also support 130 trainees. There is no increment of trainees provided for in the budget.

Senator HARKIN. Why not?

Dr. KIRSCHSTEIN. Mr. Chairman, given the competing needs for funds in the budget, no additional support for trainees was available. We did submit a plan for what to do over the 5-year period in response to questions last year.

Senator HARKIN. It was supposed to be up to 1,500 a year.

Dr. KIRSCHSTEIN. That's correct—the original plan was to provide steady increases in the number of trainees being supported under this activity, up to a level of 1,500 trainees per year, over a period of 5 years.

Senator HARKIN. Obviously, at 130 a year, we are not going to make that at all.

Dr. KIRSCHSTEIN. That's right.

COST TO SUPPORT 250 BIOTECHNOLOGY TRAINEES

Senator HARKIN. How much would it cost to go from 130 up to 250? Do you know what that would cost?

Dr. KIRSCHSTEIN. Yes, sir.

The 130 trainees in fiscal year 1990 would cost about $2.9 million, and it would take another $3 million to go to 250.

Senator HARKIN. So it's $3 million more?

Dr. KIRSCHSTEIN. Yes.

Senator HARKIN. Let me think about this. Your budget is General Medical Sciences. It is $781.3 million.

Dr. KIRSCHSTEIN. Including AIDS. There is $14.9 million for AIDS.

Senator HARKIN. Your budget increase for this year is up how much percentagewise?

Dr. KIRSCHSTEIN. Mr. Chairman, depending on whether or not one considers the funds allocated for the human genome project determines how much money one considers that the Institute's budget has increased.

As you heard from the testimony of Dr. Wyngaarden and Dr. Watson this morning, until the National Center for Human Genome Research is established perhaps in October 1989, the funds for the Genome Project are in NIGMS's fiscal year 1990 budget—$99.1 million. Without the Genome Project, the funds would actually be, instead of $766 million, $667 million. That increase from the previous year is only 3.6 percent.

Senator HARKIN. Without the Human Genome, it would be how much?

Dr. KIRSCHSTEIN. It would be $667.3 million in fiscal year 1990.

Senator HARKIN. That is actually less than what you had? I have $671 million for fiscal year 1989.

Dr. KIRSCHSTEIN. That's with the AIDS funds and with the genome funds.

Without genome funds in fiscal 1989, it is $643 million. It increases to $667 million without the AIDS and without the genome funds.

It gets very complicated.

Senator HARKIN. We have to straighten that out. I have different figures than that. But it seems like for only $3 million—well, we'll see.

What kind of priority would you give that?

Dr. KIRSCHSTEIN. I'm sorry?

Senator HARKIN. What kind of priority would you give that $3 million for this biotechnology training?

Dr. KIRSCHSTEIN. I think that is an extraordinarily important priority, sir. We will start with 130 trainees for $2.8 million. This means that those individuals will still be in training next year.

We know now that we could accommodate something on the order of 400 trainees, based on the applications we have thus far received. So we think that increasing to 250 is a very high priority.

BUDGET FOR RESEARCH TRAINING

Senator HARKIN. In view of the dominant role of your Institute in training, you fund what, two-thirds of all the pre-doc?

Dr. KIRSCHSTEIN. Two-thirds of all the pre-doctoral, pre-PhD programs. That includes the important Medical Scientists Training Program, the MD/PhD program. I should tell you that we are very proud that the University of Iowa has such a program.

Senator HARKIN. Well, then, in view of this, how concerned should we be that this year funding available for training has increased very, very slowly, and it is not keeping up with the growth in the research grants?

Dr. KIRSCHSTEIN. That is correct, and we are deeply concerned about it.

The National Academy of Sciences has a committee which studies manpower needs for biomedical research. The committee will be reporting its newest figures soon. But, based on the projections contained in its last report, in 1985, and on how many trainees it suggested that the National Institute of General Medical Sciences support, we think we are about 800 below the number we should be supporting, even without considering the new biotechnology training program.

BIOTECHNOLOGY POLICY BOARD

Senator HARKIN. What is the status of the creation of the Biotechnology Policy Board?

Dr. KIRSCHSTEIN. A charter for that board has been developed by the NIH Office of Science Policy and Legislation, which Dr. Moskowitz heads; and I believe it is on its way or is pending in the Department at the present time.

We have requested nominations for membership from the National Academy of Sciences and from a number of organizations that are involved in biotechnology. That is the status thus far.

REQUESTED 2-YEAR OBLIGATION AUTHORITY FOR GENOME FUNDS

Senator HARKIN. I asked Dr. Watson earlier about the 2-year thing for the human genome, rather than 1 year. I guess you assume that you may need to have that available to carry over past 1 year?

Dr. KIRSCHSTEIN. Yes, sir.

As the planning process that Dr. Watson told you about takes place, it seems reasonable to believe that decisions and the development of programs may take somewhat longer than a single year; and, in order to be assured that only the best research is supported in this area, along with similar research in other areas, it would seem to be that the 2-year allocation might be appropriate.

When the planning process is further along, I think Dr. Watson will be able to better determine what the real needs are.

TIME REQUIRED TO MAP THE HUMAN GENOME

Senator HARKIN. How long will it take to really map the human genome?

Dr. KIRSCHSTEIN. The original projections were about 5 years. I believe Dr. Watson has told you today that he hopes this will be done in 3 to 4 years.

The sequencing will take much longer.

Senator HARKIN. OK. But the mapping will take 3 to 4 years.

Dr. KIRSCHSTEIN. Yes; and probably 10 to 15 years to finish the total sequence.

Senator HARKIN. Why will it take that long? Could it be done in less time than that, Dr. Watson?

Dr. WATSON. We have to really develop better technology for the sequencing, and the technology is not at hand. We think there can be an improvement, but we certainly would not want to commit to it.

I'm sorry if I confused you by saying it was 3 to 4 years. I think it would be 5 years from, say, the start of 1990, to do the mapping. It is about a 5-year period for the mapping.

Senator HARKIN. Could it be done shorter than that?

Dr. WATSON. No, sir; I think it will take that long.

Senator HARKIN. So, even if you had more money, it would not collapse the time?

Dr. WATSON. No.

It will take a year of planning and getting everything operational, and so on.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. OK. We will be submitting some questions for your response.

Thank you.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

RESEARCH TRAINING

Question. The Institute of General Medical Sciences funds two-thirds of the pre-doc training slots and one-third of the overall training slots.

Are we "eating too much of our own seed corn" in the sense that we are not planning well for the future by training so few people and by giving training such a relatively low priority in all the institutes at NIH?

Answer. I believe that research training is highly important, because it represents our country's investment in its future. For this reason, I feel that it deserves an extremely high priority at NIH and elsewhere. It must be noted, however, that while NIH has given top priority to funding research project grants in recent years, we are still in the position of being able to support less than 30 percent of the meritorious research grant applications being received. It is difficult for me, therefore, to suggest a reduction in the support for research project grants in order to support more training.

AIDS RESEARCH

Question. Dr. Kirschstein, your Institute conducts some of the most basic research regarding the structure and function of cells and sub-cell components. I understand that some of the most promising AIDS research relates to cell structure. Could you tell us about that and what role your Institute has played in AIDS research?

Answer. There are several proteins involved in the disease-producing effects of the AIDS virus. The CD4 receptor protein, for example, represents the "docking site" on the host, or "victim" cells, to which the AIDS virus must attach itself prior to penetration of these host cells. Research teams supported by the NIGMS' Biophysics and Physiological Sciences Program are currently using X-ray crystallography and other techniques to obtain a detailed knowledge of the three-dimensional structures of these proteins, with the goal of developing ways to disrupt their activity. Researchers believe that once the structure of the CD4 protein is known, for example, it will be possible to develop an approach to blocking access to this receptor by the AIDS virus or, alternatively, to develop the ability to produce synthetic CD4 proteins that could be used to lure the AIDS virus away and prevent the invasion of healthy cells. The President's FY 1990 budget request provides approximately $9.1 million for AIDS research activities supported by the NIGMS, an increase of about $3.6 million over FY 1989.

FUNDING FOR HUMAN GENOME PROJECT

Question. The $100 million requested for the Human Genome research initiative is requested to be made available through September 1991. In other words, the request is to make those monies available for two years while the other funds within the Institute are available for only one year.

Why do you need a two year availability for the Genome Research Project? Can we assume that you do not feel you can obligate the entire amount in the one fiscal year?

Answer. As Dr. Watson, the Associate Director of NIH for Human Genome Activities, testified before the Committee, it is NIH's plan to obligate the entire $100 million requested for FY 1990 in one year. Because of the rapid expansion of this program, however--from $27 million in FY 1989 to $100 million in FY 1990--as well as the time required for planning, announcement, and review activities, there is a chance that obligation of the full amount by September 1990 will not be possible. With this in mind, two year obligation authority was requested.

Question. The original plan was to increase spending in equal increments over 5 years until the annual funding reached $200 million a year--or growing at $40 million a year. Why have you accelerated the rate?

Answer. As Dr. Wyngaarden noted in testimony before the House Appropriations Committee, NIH initially requested $62 million for support of the Human Genome Project in FY 1990, compared to $27.6 million in FY 1989 and $17.2 million in FY 1988. The Administration increased the support level to $100 million, however, on the strength of faster than expected technological and scientific developments in the fields of gene mapping and gene sequencing--developments which suggested that a higher level of funding was appropriate. It is noted that, in its 1988 report on the Human Genome Project, the National Research Council of the National Academy of Sciences recommended a funding level of $200 million in the third year of the Genome program.

PROGRESS MADE IN GENOME-RELATED RESEARCH

Question. The human genome project, as initiated at NIH in 1988, plans to map and sequence the entire human genome. Although this is a multi-agency effort, NIH has taken the lead, and was appropriated $27.6 million in FY89 and has requested $100 million in FY90 for this project. NIGMS represents the institute to which these funds were appropriated.

What progress has been made during the past year on the human genome project?

Answer. A great deal of scientific progress has been made during the past year. Significant advances have been obtained both in NIH-supported research and in work supported by other agencies and organizations which are committed to the project. This is, in part, reflective of additional progress that has been made in developing means of coordinating the efforts of the many parties interested in the project. Highlights of the scientific achievements made include qualitative improvements in methods of gene localization by in situ fluorescence mapping, physical mapping of chromosomes by use of hybrid cell lines, and genetic mapping by analysis of meiotic recombination in single sperm cells. Improvements have also been made, through the use of automated DNA sequence instruments, in the rate at which DNA sequences can be determined. This progress owes much to the enormously successful outcome of research projects in

the general area of genetics and molecular biology supported by the NIGMS. A new technique developed by NIGMS grantee, Dr. David Ward of Yale University, for example, is expected to make it possible for a team of five people to map up to 5,000 genes in only two or three years.

ROLE OF THE OFFICE OF HUMAN GENOME RESEARCH

Question. What effect, if any, has the Office of Human Genome Research, established recently within the Office of the Director, had on NIGMS functions in this area?

Answer. The Office of Human Genome Research, OHGR, was established for the purposes of coordinating research activities in genomic analysis and developing plans and policies for the Human Genome effort. The OHGR has been responsible for setting up and organizing the meetings of the NIH Program Advisory Committee on the Human Genome, which is charged with advising the NIH on all aspects of research in genomic analysis. Currently, the Office is engaged in organizing the development of a research plan for the national Human Genome Research Program effort. The OHGR has also been active in promoting interaction and communication among the several national and international agencies interested in the genome program. These include the National Institute of General Medical Sciences (NIGMS), the National Library of Medicine (NLM), the Department of Energy (DOE), the National Science Foundation (NSF), the Howard Hughes Medical Institute, the European Economic Community, and a new international scientific society, the Human Genome Organization (HUGO). Finally, the OHGR staff have interacted extensively with the staff of NIGMS in support of NIGMS' activities with regard to management of appropriated "Genome" funds.

It should be noted that the NIH is currently awaiting approval from the Office of the Secretary of a proposal to reorganize the OHGR into a National Center for Human Genome Research. If approved, the new Center would assume responsibility for administering all aspects of the Genome Project.

Question. What type of projects will be funded during FY90 and who will make these determinations?

Answer. The funds requested for FY 1990 will be used to support a variety of projects. Investigator-initiated research project grants and program projects, which have been the primary support vehicles during the first two years of the genome project at NIH, will continue to be an important component of NIH-sponsored genome research. In addition, several new aspects of the program are planned for introduction in FY 1990. One is the support of scholarly research and public discussion of the social, ethical, and legal ramifications of human genome research. The NIH Program Advisory Committee established a working group in this area and a solicitation for grant applications has already been published. Another new element will be Human Genome Research Centers. The details of this program are currently being discussed by the Program Advisory Committee. The OHGR expects to fund three such centers in FY 1990. A final major new initiative will be a genome training program. The design of each of these components is being developed with advice from the

Program Advisory Committee on the Human Genome and through discussions that the OHGR is holding with NIGMS, other parts of NIH, and other interested agencies and parties. Funding decisions will be made, in all cases, on the basis of advice obtained through the peer review process.

Question. What collaborative efforts are in progress with other Institutes and agencies?

Answer. The NIH has established a Coordinating Committee on the Human Genome to promote communication and interaction on human genome research among the various institutes within the NIH. Through this, and other channels, several Institutes have expressed interest in developing intramural research programs that are relevant to the Human Genome Program. Among these is the National Center for Biotechnology Information (NCBI) of the National Library of Medicine. Frequent discussions and collaboration between NIGMS, OHGR, and the NCBI have taken place concerning the present and future data management needs of the Human Genome Program, including the technical limitations in biological information retrieval (both database and analysis, theory, and practice) that are not likely to be addressed outside the genome effort. NIGMS and OHGR have also been closely involved in discussions and coordinating efforts with the Office of Health and Environmental Research of the Department of Energy, with the National Science Foundation, and with the Howard Hughes Medical Institute. These organizations have, for example, jointly sponsored several workshops on aspects of the genome program, and the staff of these groups meet on a regular basis with both NIGMS and OHGR staff. Internationally, discussions have taken place between NIH staff, the staff of the European Economic Community, and with Japanese scientists.

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICESHIP PROGRAM

Question. A letter to the editor appeared in the Washington Post (February 7, 1989) stating that a 13-year old high school student was selected for, but unable to accept a "minority research apprenticeship program" position which was funded by the NIH. The writer claimed that because Federal labor laws disqualify the employment of minors under 14 years of age, the student was not allowed to participate.

Have there been other reports of frustrated attempts by younger high school students to participate in NIH programs due to Federal labor laws that prohibit their employment?

Answer. The Minority High School Student Research Apprenticeship Grant Program is a component of the Biomedical Research Support Program administered by NIH's Division of Research Resources (DRR). The purpose of the program, which is unique at NIH, is to provide minority high school students with a meaningful work experience in health-related research, in order to stimulate their interest in science careers. DRR staff have informed us that the case you mention, which occurred at the University of Michigan, is a very unusual one, in that almost all of the students who apply for positions under this program are 17 and 18 year-old high school juniors and seniors. It is rare to find a student as young as age 13, who is ready to tackle such a position. A total of 8,000 students have

been selected for positions under the Apprenticeship Program since its inception, and this is the only problem case of which DRR is aware.

Question. What progress has been made in the recruitment of trainees for this year's positions?

Answer. All of the 1,116 slots to be supported under this program during the current fiscal year have been filled, with no problems that we know about.

SHORTAGE OF UNIVERSITY RESEARCH SCIENTISTS

Question. You stated that the supply of well trained university professors is expected to dwindle as the present population reaches retirement age. Are there any specific populations other than pre- and post-doctoral trainees that can be considered for training (e.g.,high school teachers)?

Answer. While many high school teachers could probably teach college level courses in the sciences, the real problem is the need to maintain an adequate pool of well trained Ph.D.-level research scientists. It is important, therefore, to make sure that we, as a Nation, are training an adequate number of future scientists, individuals who are well-educated in modern science at both the predoctoral and postdoctoral levels, no matter from what milieu they move to seek such training.

There is a population from which we can draw, however, and that is the country's minority population. A recent Department of Commerce report, Workforce 2000, clearly indicates that the Nation's non-white minorities are coming to represent a larger and larger proportion of those entering the country's workforce for the first time. These are people who, in the past, have not entered biomedical research careers in great numbers. However, if we are to maintain the momentum we have built up in the biomedical research field over the past several decades, we now need to greatly increase the number of minorities entering into science careers.

MINORITY ACCESS TO RESEARCH CAREERS PROGRAM

Question. Are there plans to restore the number of Minority Access to Research Careers (MARC) program trainees to its FY87 level?

Answer. The President's budget request provides approximately $9.6 million to support 507 trainees under the MARC Program in FY 1990. This exceeds the $8.6 million obligated under this program in FY 1987, for the support of 480 trainees.

EFFECT OF BUDGET LIMITATIONS ON RESEARCH INITIATIVES

Question. An editorial in the New York Times (February 6, 1989) suggests that some science projects be reconsidered in light of their expense and the Federal budget deficit.

How would budget reductions affect such research as the human genome project, AIDS, and biotechnology?

Answer. The President's budget request for FY 1990 provides $100 million for the Human Genome Project and $753 million for AIDS-related research activities at NIH. In addition, practically every Institute at NIH supports genetics research that may be defined as biotechnology. These, indeed, represent substantial investments of taxpayer money. But, reducing the level of funding available for any research program would do the obvious; that is, slow the pace of research and research discoveries expected from the program, and ultimately delay the availability of effective new methods of disease diagnosis, treatment, and prevention. Personally, I feel that the investment of funds in biomedical research today means a savings of money for the Nation in the future. For example, much of the savings will come from the creation of jobs in the new biotechnology industry--an area in which the United States is already competing with the Japanese. Other savings are likely to result from reducing the enormous burden on our health care system caused by the 4,000 or so genetic diseases that afflict mankind. Currently, an estimated 15 to 20 percent of the total expenditures for health care in the United States are associated with genetic-related disorders.

Question. To what extent will new programs such as the burn and trauma research center and Methods to Extend Research in Time (MERIT) awards be affected by the current Federal fiscal situation?

Answer. The current fiscal situation is having very little effect on the Institute's ability to fund either new research center grant awards or MERIT awards. The NIGMS expects to fund six burn and trauma research center grants in FY 1989, for example, instead of the seven funded in FY 1988, because the applications received by the Institute were not judged, during peer review, to have high scientific merit. MERIT awards are made to only the most outstanding, world renowned researchers, with project periods of seven to ten years. No single year funding situation, therefore, is likely to have much effect on the limited number of these awards the NIGMS is likely to make. Funding limitations have, however, impacted on the Institute's ability to support both new and competing non-Genome research project applications and additional research trainees.

Question. If budgetary restrictions had to be accommodated for all activities at the NIGMS, how would you decide which programs would receive the most, and which programs would receive the least, attention?

Answer. The primary mission of the NIGMS is to support basic research and multi-disciplinary predoctoral research training. Because of this, the Institute allocates most of its available funds to research project grant awards (83 percent) and National Research Service Award training awards (10 percent). The Human Genome Project aside, research funds are allocated to the Institute's four major programs largely on the basis of past experience. This experience tells us the likely proportion of grants that each program will receive in terms of high quality research proposals; i.e., about one-third each to the Genetics and Cellular and Molecular Basis of Disease Programs, and one-third to the Pharmacological Sciences and Biophysics and Physiological Sciences Programs. These general parameters would be used to allocate either budget cuts or budget increases, with the understanding that we will always try to be responsive to exciting new developments in any field in which

they occur. It should be emphasized that the allocations made to the Pharmacological Sciences Program, which supported four Nobel Prize winning researchers in the past dozen years, and to the Biophysics and Physiological Sciences Program largely reflect the level of research activity in the community and does not suggest, in any way, that research in these areas is less important.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

PHARMACOLOGICAL SCIENCES TRAINING

Question. Dr. Kirschstein, how many training slots were available for the pharmacological sciences in FY89?

Answer. We currently estimate that 315 research trainees will be supported by the Institute's Pharmacological Sciences Program in FY 1989. This number will increase to 348 trainees, however, if a pending request for reprogramming is approved.

Question. How many were available ten years ago?

Answer. In FY 1979, 586 trainees were supported by this program.

Question. Why are so many fewer training slots available today?

Answer. During the period 1979-1988, the total number of research trainees supported by the NIGMS in its four regular research training programs--pharmacological sciences, cellular and molecular biology, genetics, and systems and integrative biology--decreased from 3,060 to 1,967. This decrease has come about primarily as a result of steadily increasing tuitions, in the face of essentially constant training dollars--a problem compounded by the fact that it has been NIH policy to pay the full tuition requested by each university. Thus, during the time period in question, all of the research training programs supported by the NIGMS--with the exceptions of the Minority Access to Research Careers (MARC) and the Medical Scientist (M.D.-Ph.D.) Training Programs--suffered a steady erosion of training slots. An NIH decision to increase trainee stipends in FY 1989, further reduced the number of trainees that could be supported; but the proposed reprogramming is designed to ameliorate the effect of this particular action.

NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DR. DONALD LINDBERG, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next is the National Library of Medicine, and Dr. Lindberg.

Dr. LINDBERG. Senator Harkin, it is a pleasure to be with you.

The task of the National Library of Medicine is to acquire, organize, and disseminate the biomedical literature of the world for the benefit of the public's health.

The Library did this for about 150 years, using traditional manual library methods. However, since about 1964, NLM has invested very heavily in computer technology. The increase in the amount of knowledge, and the importance of getting knowledge to health care practitioners in a timely fashion prompted the use of computers.

The research that NIH conducts and supports, that the Congress funds, and that the country counts on, would be totally useless if that information was not organized and made available to those who need it. It is that organization, that infrastructure, so to speak, that is the task of the National Library of Medicine.

Last year, the Health Omnibus Program Extension Act authorized expansion of NLM's functions in three particular areas. The areas are biotechnology, AIDS, and outreach. I will highlight the progress that the Library is making in implementing these initiatives.

NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

First, the National Center for Biotechnology Information was created by the Congress has been established organizationally within the Library. This organizational change has been approved formally by NIH, and by the Department. The center's Director is in place.

The center has numerous responsibilities. Broadly speaking, the center coordinates and integrates the existing data bases and computer services. Also, it conducts research intramurally and funds extramural research project grants. The purpose of this research is to develop new methods that will be essential in keeping pace with the great increases in knowledge coming from the experimental laboratories that Dr. Watson has projected.

AIDS INFORMATION SERVICES

Second, with regard to AIDS, the legislation gave certain responsibilities to CDC, FDA, NIAID, and to NLM. The Library is authorized to create and maintain an AIDS research data bank.

Even prior to the enactment of this legislation, NLM developed a printed AIDS bibliography. Subsequent to that, the Library has essentially put that database online. Presently, NLM is enriching this AIDS information service to include bioethics information, cancer literature, and other relevant databases that currently exist in Federal agencies.

In the future, if the Library can get the support, it will further enrich the bioethics and biochemistry aspects of NLM's AIDS information services.

OUTREACH PLANNING PANEL

Third, the Congress, particularly this committee, gave NLM statutory authority, to publicize the availability of the products and services of the National Library of Medicine. We have taken that charge very seriously.

In order to effectively respond to the congressional mandate, the Library's Board of Regents established a special long-range planning panel. The 31-member panel includes distinguished health care practitioners, management representatives, librarians, computer scienctists, and many other distinguished people from other disciplines. It is chaired by Dr. Michael De Bakey, who, in addition to all his other numerous medical accomplishments, chaired the President's Commission on Heart Disease, Cancer, and Stroke back in 1964. As a direct result of that panel's report, the Medical Library Assistance Act was created. The authority provided in the act allowed NLM to form the Regional Medical Library Network in the United States.

Essentially, in Dr. DeBakey's view, the panel is assessing how far the NLM has come in the last 25 years. It is a long way. It can be said that the resources of the libraries have been pretty well addressed. They were considered to be disastrous in 1964, at that time collections and other resources were inadequate. Also, at that time, there was no way to share resources between the libraries, even though they wanted to. Today, there are systems in place to facilitate sharing.

In addition, there was no way to assure that a health care practitioner in the United States could get information to help his or her patient, regardless of the location. That too, has been remedied.

In those 25 years, the Regional Medical Library Network has essentially become the envy of the world. The United States is the only country with such a network. I receive visitors at least twice a week from abroad who really want to know how to build this type of infrastructure.

Dr. DeBakey's panel report essentially says that NLM must concentrate on enhancing the health professionals' access to biomedical information. The Congress and NLM have done a very good job in providing resources and strengthening institutional networking. Now, it is time to facilitate the individual health professionals access to NLM's information services and products.

Doctors now have computers, the country has a much better telephone system, and all of these technologies work better and faster than ever before. Now, we have to get all of those individuals accessing the information available in the NLM.

The Outreach Panel recognizes that health professionals would benefit greatly from accessing NLM information systems. Therefore, the panel recommends that NLM conduct an extensive outreach program.

Senator Bumpers spoke about wanting a scheme in which one could--dial in, look in, or push a button, as he spoke of it, to get some relevant information about a treatment. I wholeheartedly support that concept.

In fact, I have spent most of my professional career trying to develop exactly those systems. In some respects, it is easier said than done, of course. But that is our task, and that is the kind of research that NLM conducts and supports.

I am as proud as Dr. Broder of the PDQ system in cancer. That system was developed by NCI and NLM jointly. The subject matter expertise resides wholly with the Cancer Institute, but the knowledge of how to build the system was an NLM contribution and one that I am proud of.

PREPARED STATEMENT

Dr. DeBakey and his group studied the question: Why don't more people use the NLM information systems? They are good systems and the people who use them including patients whose doctors use them benefit. The question remains—why don't all health professionals use NLM information systems?

Dr. Broder's predecessor, Dr. Vince De Vita, used to say that 40,000 patients a year die needlessly of cancer because they get started on the wrong treatment protocol. The knowledge of the right treatment protocol is in that system.

[The statement follows:]

STATEMENT OF DR. DONALD LINDBERG

Mr. Chairman and distinguished members, it is always a special pleasure and privilege for me to appear before your Subcommittee. As we have discussed over the years, the increase in knowledge and advances in health care resulting from our Nation's investment in biomedical research would be of limited value if it were not for the National Library of Medicine's (NLM) function of organizing and providing access to biomedical information. In order for the Nation to reap the benefits of the ever increasing growth of scientific knowledge, NLM invests both its fiscal and intellectual resources not only in acquiring this information, but in devising new and more efficient and effective methods for making it readily available to the health and science community, and preserving the literature for future generations. The primary goals of these activities are to enhance medical research, education, and practice, and thereby improve the public's health and quality of life.

In 1988, the National Library of Medicine experienced a significant expansion of its responsibilities in the areas of biotechnology, AIDS, and outreach. Last year, funds were appropriated for the Library to support and conduct biotechnology information systems initiatives, and legislation was signed into law directing the formal establishment of the National Center for Biotechnology Information at the Library. That same legislation also directed the Library to work with other Federal agencies to develop and make available a data bank containing the results of AIDS research being conducted around the world. We have initiated action in each of the areas emphasized.

The National Center for Biotechnology Information has been established as a divisional component of the NLM. The Center's mission is to create automated systems for knowledge about molecular biology, to conduct research into advanced methods on how to handle biotechnology information, to enable those engaged in biotechnology research and in medical care to use the systems developed, and to coordinate the gathering of biotechnology information worldwide. As you are aware, the importance of computer and information science as applied to the human genome continues to grow; computer databases for biotechnology are swelling rapidly with new molecular data. The new Center will provide enhanced biotechnology information services to assist researchers in analyzing, recording, and retrieving genetic molecular data accurately and comprehensively.

The promise of the human genome project is indeed profound. This major NIH endeavor is intimately dependent upon computers for the representation, communication, and analysis of data. The National Library of Medicine remains committed to facilitating the human genome initiative, and to fostering the application of advanced information technologies to the molecular life sciences. Recently, NLM issued a request for

applications to support research into advanced information systems in support of biotechnology and the Human Genome project. Intramural research on this topic is also being done. For example, the GenInfo Workstation currently being tested will allow a researcher to ask a question in his own words and have his question answered by information retrieved simultaneously from multiple databases containing molecular data, including NIH's GENBANK. After testing by NIH researchers, GenInfo will be made available to health professionals around the country. In addition, the Library is now building a "database of biotechnology databases" that will help scientists to locate not only molecular biology information but also such resources as tissue banks, clone libraries, and enzyme data banks. This resource will be made available in both printed and computerized form during 1989.

With regard to AIDS information needs, the recently enacted Health Omnibus Program Extension of 1988 calls for the Library's involvement in the establishment of "a data bank on information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries." Even before this legislation, NLM laid the foundation for such a data bank by initiating several bibliographic services, such as the AIDS Bibliography.

Earlier in 1988, NLM created AIDSLINE, an online bibliographic service which now contains some 15,000 references to scientific articles about AIDS. References in AIDSLINE cover both the clinical and research aspects of AIDS and AIDS-related diseases, organisms, drugs, epidemiology and health policy issues. Under the impetus of the new Act, NLM will begin to expand AIDSLINE this fiscal year to include citations from other important databases such as the Health Planning and Administration database, CANCERLIT, and BIOETHICS. We will also add information from major AIDS meetings.

In addition to starting these bibliographic services, the Library also initiated other activities to assist users in finding information about AIDS. NLM's online directory service, DIRLINE, was enhanced with references to some 300 national organizations that can provide information and services regarding AIDS. This was done in cooperation with the National AIDS Information Clearinghouse. Furthermore, NLM has initiated collaborative work with the National Institute of Allergy and Infectious Diseases to mount in 1989 on the NLM system a new database on AIDS Clinical Trials for online access.

NLM's statutory responsibility was recently revised to include authority for NLM to "publicize the availability of the products and services of the National Library of Medicine." We acknowledge that more efforts to increase awareness of our products and services should be made. We welcome the challenge this brings us. To help chart our course in this area, we recently convened an Outreach Planning Panel. The Panel is

chaired by the world famous heart surgeon, Dr. Michael DeBakey, and includes experts in management and marketing, health professionals, librarians, and representatives of health and related associations.

The primary goals of the Panel are to increase awareness and use of NLM products and services among rural and urban health professionals, faculty and students in academia, and the media; to define the outreach role of NLM's network of seven geographical Regional Medical Libraries; and to establish mechanisms to determine the utility of current NLM products and services. I am especially encouraged by the commitment of the Panel members and the good work that they have done. A final report containing the recommendations for an NLM Outreach Plan will soon be completed.

Even prior to the advent of the Panel, NLM recognized the need to expand the use of its services. Some of our major ongoing initiatives include improving GRATEFUL MED's capabilities, and broadening the service activities of the Regional Medical Library Network. More specifically, we recently released an updated version of GRATEFUL MED which is more user friendly than its predecessor, and we have significantly increased the number of access codes issued. In addition, NLM and the Regional Medical Library Network have begun to examine the administrative and technical issues related to the use of DOCLINE by individual health professionals and researchers. Developed to improve services to health professionals, DOCLINE is an automated system which rapidly routes the millions of interlibrary loan requests in the U.S. to the closest available source within the Regional Medical Library Network.

Biotechnology, AIDS, and outreach are just a sampling of some of the major areas of emphasis at the NLM. Initiatives in Integrated Academic Information Management Systems (IAIMS), Medical Informatics, Unified Medical Language, and Preservation are important as well.

As you have heard in the past, Integrated Academic Information Management System awards assist health science centers to plan and develop institution-wide communication networks to link library and other individual and institutional databases and information systems, within and external to the institution, in order to enhance patient care, research, education and institutional management. As part of the long-term development of IAIMS, we plan to award two Phase-III grants to develop prototype systems in FY 1989.

The Library will this year initiate a program of individual medical informatics fellowships. These fellowships will make it possible for talented individuals to take advantage of learning opportunities at leading American universities in addition to the seven universities that already have medical informatics training programs under NLM grant support. Although small, this program will contribute significantly to enhance the training opportunities in medical informatics by

increasing the flexibility in the use of the Nation's resources for training purposes. These fellows may also round out their post doctoral training by concentration on some specialized part of medical informatics such as expert system applications to the mapping of the human genome.

NLM's Unified Medical Language System project is helping to dissolve barriers to the widespread use of computer-based information systems in medicine. This is not being done by imposing a single standard vocabulary on all systems and users, but by developing knowledge sources that can be used by computer programs to interpret and translate the language of clinical health care users into terms that serve to control automated biomedical information systems.

Preserving literature for future generations remains a high priority initiative as well. NLM is continuing to implement the recommendations of its 1985 Preservation Plan, which include preservation of NLM's own collection, identification and preservation of important biomedical publications held in other U.S. institutions, and a campaign to reduce the size of future preservation problems by influencing biomedical publishers to use more permanent acid-free paper in their publications.

In conclusion, the availability of biomedical information is critical to the promotion of the Nation's health. As such, it is paramount that the information be available when and where it is required and in a form that can be readily used. There are a number of opportunities on the horizon in information technology services that have the potential to enhance medical education and practice, such as electronic imaging and expert systems. As the nerve center of the Nation's biomedical information network, the National Library of Medicine is helping to ensure that the country capitalizes on the information technologies at hand while positioning itself to foster and generate those of tomorrow.

Mr. Chairman, the FY 1990 request for the National Library of Medicine is $78,229,000. I shall be pleased to answer questions you may have.

INFORMATION SYSTEMS USAGE

Senator HARKIN. Why don't they use it?

Dr. LINDBERG. In most cases they don't know these information systems and services exist. In many other cases, they don't know how to or are afraid of using a computer.

Senator HARKIN. Now you're just talking about the PDQ system?

Dr. LINDBERG. No; a lot of NLM systems, as well as the cancer system, are underused. An outreach effort or initiative in the DeBakey committee's view is essential to effectively address this problem.

Senator HARKIN. Wait a second. Let me back you up.

You have the MEDLARS system, right?

Dr. LINDBERG. Yes.

Senator HARKIN. I'm told that in Iowa, we have about 1,200 practicing physicians, and only 100 have subscribed to that system.

Dr. LINDBERG. Well, when I came to NLM, there was only one. It has increased.

Senator HARKIN. How long ago was that?

Dr. LINDBERG. Four years ago. So, it has increased 10,000 percent, if you want to express it in percentage terms. Nevertheless, I am not satisfied with that progress.

Senator HARKIN. Well, why aren't they subscribing? Is it because they don't know about it?

Dr. LINDBERG. Yes; in part.

USAGE COST

Senator HARKIN. How much does it cost? Is it too costly?

Dr. LINDBERG. It costs nothing to subscribe to it.

We have actually produced a product, GRATEFUL MED, that allows doctors to access NLM information systems right from their offices. We sell it at cost, for $29.95. So, it is not a financial burden.

Individual calls for patient-related problems cost just a dollar or two. Again, it is not a financial problem.

A major concern is that most doctors in practice did not have any formal instruction on the use of computers while attending medical school. This is evidenced by the fact that there is not a medical school now that provides proper training in medical informatics.

We know that most doctors have computers for patient accounting and appointment making. And, we know the conversion to using computers to access NLM information systems is pretty easy. But, someone has to instruct and assist health professionals initially.

Medical librarians and the NLM Regional Medical Library network are at least part of the answer. They are the change agents that are needed.

NLM does not have field staff. So, the Library cannot do it. We have to rely on and work through others.

PUBLICIZING PRODUCTS AND SERVICES

Senator HARKIN. This committee basically directed you, gave you specific authority to publicize it. You talked about the panel that was set up.

Dr. LINDBERG. Yes; the Board of Regents has established an Outreach Planning Panel.

Senator HARKIN. What are you going to do differently next year?

Dr. LINDBERG. We are awaiting the panel's final plan before deciding exactly what to do. In the meantime, the Library has increased its participation in scientific meetings in an effort to increase the awareness of NLM's products and services.

HOSPITALS AND LIBRARIES LINKAGE

Senator HARKIN. Doctor, let me ask you this question.

States license doctors. I have to believe that being able to access this system and to understand it would just be an immense help to practicing physicians anywhere and would, as you say, go after some of these needless deaths that occur because they got the wrong treatment in the beginning.

Have you ever examined the possibility of maybe asking State legislatures to mandate, as a part of the licensing requirement, that doctors be required to have an understanding of the system and to subscribe to the system?

Dr. LINDBERG. Well, the Federal Government is moving in exactly the opposite direction. Currently, hospitals are no longer required to maintain libraries to be accredited for HCFA reimbursement. That is a step absolutely backwards.

Senator HARKIN. HCFA requirements do not?

Dr. LINDBERG. Hospital libraries are no longer required. Consequently, that portion of overhead is not reimbursed by the HCFA per diem.

Senator HARKIN. When was that changed?

Dr. LINDBERG. Final regulations were implemented in the late 1970's.

NEED FOR HOSPITAL LIBRARIES

Senator HARKIN. Do they need the library if they can access you?

Dr. LINDBERG. Well, frankly, they need both.

Senator HARKIN. Wait a second. If they have this system set up, why do they need a library?

Dr. LINDBERG. Well, the world of the future is not quite here. The MEDLINE system is the most heavily used bibliographical computer database in the world. It provides names, titles, authors, and in many cases abstracts. It gives you most of the information that you want, but not the full text of the article. The system, of course, is very large with some 11 million references.

In the case of PDQ, it has a smaller set of entries. But, they are very detailed and very factual. It is designed to provide all of the facts that you need right then and there, plus the telephone number of a consultant.

PDQ and MEDLINE really have two different purposes: One is factual and the other bibliographical. There is no computer in which everything you need to know resides.

MANDATING HOSPITAL LIBRARIES

Senator HARKIN. Well, aside from the fact that the Federal Government backed off on accreditation of hospitals to maintain a library, why does that argue against maybe asking the States to mandate? Does any State do that? Does any State mandate that they have to belong to the system?

Dr. LINDBERG. No; probably the closest to that is the continuing medical education that is required for certification in certain specialties.

It is more likely that the National Board of Medical Examiners would move nationally to test information-seeking skills than for 50 jurisdictions to change their State licensure.

Senator HARKIN. Would you say that again?

Dr. LINDBERG. In my opinion, it is more likely for the National Board of Medical Examiners to address this need at a national level, than for 50 States to act independently. But, hopefully, that won't even be necessary.

NLM's computer system receives 4 million calls a year. We know that about 51 percent of these searches are for patient care problems.

I think that total number can grow, if we develop an effective outreach program to explain these systems to doctors close to their place of practice.

INCREASING PHYSICIAN USAGE

Senator HARKIN. You've gone from 1 to 100 in 4 years in Iowa, and we have 1,200 there. At that rate, it will only take us another 40 years to get there.

Dr. LINDBERG. Well, maybe we can double up and work a little fast.

Senator HARKIN. Then it will still take 20 years.

Dr. LINDBERG. I think it can go faster than that. I really do.

But, we have to do more than sit in Washington. Again, Outreach is the key.

Senator HARKIN. Well, I'll tell you, I just hit upon that idea. I think State legislators ought to be asked to examine whether for continuing medical education, which they require, and for their licensing requirement that they require they understand the system, know how to use it, and have the necessary equipment in order to be able to access it.

It does not cost much for the equipment, right?

Dr. LINDBERG. That is true, plus most physicians already have computers in their offices. This equipment is less available amongst libraries.

Senator HARKIN. I wonder what the AMA would say about that?

Dr. LINDBERG. AMA is very strongly in favor of these on-line information systems. There is an AMANET which connects to us, as a matter of fact. So they recognize the need as well. As you know, changing peoples' way of doing things is hard and takes time.

OUTREACH

Senator HARKIN. Again, last year this committee requested that the Library develop an active outreach program for rural areas, for rural and underserved areas.

Dr. LINDBERG. Yes; NLM is actively carrying out that directive.

Senator HARKIN. Again, it would seem to me that this is one way of doing that.

Dr. LINDBERG. Yes; one of the things we have done is we significantly increased NLM presentations at professional meetings. Here we run immediately up against an FTE limitation. NLM simply does not have the people to do that ourselves.

The Library has initiated contracts so that we can have others help explain our products and services.

We have created a front-end software package for on-line searching which helps to extend NLM services to rural areas.

In addition to that, the DeBakey panel suggests that NLM enhance its Regional Medical Library Network and work through those institutions that already exist there by creating a kind of field staff, to reach out to the rural areas. That is really the direction in which we are headed.

EXTRAMURAL PROGRAMS

Senator HARKIN. Finally, let me ask you about the extramural research program.

You asked for $14 million. Since these do not fund biomedical research as do grants from the other institutes, what is the purpose of this Extramural Grant Program? Why do you have it? What does it do?

Dr. LINDBERG. The Extramural Grants Program of NLM is in every respect exactly like those of the other NIH Institutes. It is managed exactly according to NIH rules, including peer review with a study section and a council approval process.

NLM's extramural program has four major components. The first category is extramural research and training support for the use of computers in medicine. Currently, there are eight training grants. Together these grants support a total of about 75 trainees. It should be doubled, but that is what we have at the moment. Also, we have individual fellowships, this initiative was started just recently. In addition, NLM supports the traditional NIH research project grants.

I will highlight some examples of the kinds of computers in medical research that NLM supports. As you would expect, they run the gamut. One is artificial intelligence based expert consulting systems. These are kind of dramatic. Essentially, they are designed to give the on-line consultation that Senator Bumpers was referring to earlier. That is exactly what these systems can be helpful in doing.

There are also systems for interpretation of magnetic resonance imaging and radiology, and studies of physician use of literature in decision-making. These are examples of the first category, which is about $8 million.

The second category is the U.S. Regional Medical Library Network [RML]. This network consists of the NLM, seven regional

medical libraries, 125 resource libraries, which, of course, would include the medical schools, such as Iowa, and 3,000 local biomedical libraries.

Federal support of the RML network is the NLM at the level of $2.6 million. It is approximately the same amount of money that was put into that network in 1969 and less than the amount in 1976 when the program was funded at a level of over $3 million.

This network of libraries perform some 2 million interlibrary loans and make literature available close to the site where the doctors and patient need it.

The third category is biotechnology information research. This program is just 2 years old. There is about $2 million allocated to this program. NLM grantees at Yale University and Los Alamos National Laboratory are working on chromosome mapping. Protein sequence analysis is underway at UVA, Cold Springs Harbor, and Georgetown.

Finally, NLM's Extramural Programs support library infrastructure functions. There is about $4 million in total devoted to this program. I will mention some of the program components.

At NIH, NLM is the only organization that provides support for publication grants. The same is true of the history of medicine grants. Again, these are small programs but NLM is the only one at NIH providing this type of support.

Hospital library consortium grants are significant as they allow small hospital libraries to help one another via shared information resources. This is particularly useful in rural area settings.

NLM needs to serve hospital libraries better. We do a rather good job in the large and medium sized hospitals, but, NLM is not doing as good a job in the really small hospitals. But we try.

The Library does fund small hospital library access grants although, these grants are not big enough and not numerous enough. NLM also supports Integrated Academic Information Management Systems grants. Basically, a small number of the leading med centers, through this support plan, develop and implement information services across the institution.

Thse various funding initiatives round out the NLM Extramural Program. As you indicated, it is pretty small and pretty varied. And, I think it is also quite good.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Lindberg.

That concludes our panels for this morning.

Dr. Wyngaarden, again, thank you very much and thanks to all the Institute Directors who are here.

There will be some additional questions which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ONLINE COMPUTER ACCESS

Question. The National Library of Medicine is the world's largest medical research library. Over the years the material in the Library has been indexed into a family of data bases known as MEDLARS (Medical Literature Analysis and Retrieval System) which can be accessed across the country by individuals or institutions who have subscribed to the system and who have IBM compatible personal computers. In Iowa where we have about 1,200 practicing physicians, only 100 have subscribed to the system. With 400,000 doctors nationally, only 10,000 individuals have subscribed. Dr. Lindberg, this Committee has given you specific authority to publicize your products. What are you doing to get more people signed up to use your system?

Answer. After receiving specific congressional authority to publicize its products, NLM took several immediate steps to increase the number of users of its systems.

Activities currently underway include: an expanded program of exhibits, demonstrations, and training seminars at national and local health professional meetings using staff from NLM and the Regional Medical Libraries; direct mailings about NLM products and services to health professionals; distribution of brochures, order forms, and online application packets through health sciences libraries throughout the U.S.; development of GRATEFUL MED training courses and materials to be used in medical libraries and health professional schools; and publication of articles about the use of the NLM system in health professional journals.

NLM has conducted a baseline survey of individual users of NLM's online system to identify their demographic characteristics, how and why they use the system, and their level of satisfaction with its capabilities. The Library is currently carrying out a study using the critical incident technique to determine the actual impact on patient care and research of information retrieved. These studies have provided data that will assist NLM in improving GRATEFUL MED's capabilities so it will appeal and be useful to an even greater range of users. The availability of a version of GRATEFUL MED for MacIntosh computers, scheduled for 1989, will also make use of NLM's system more attractive to a large number of potential users.

In addition, the Board of Regents established an Outreach Planning Panel, chaired by Dr. Michael DeBakey, to develop a more effective general strategy for ensuring broader access to NLM's information services. The Outreach Planning Panel has recommended a variety of actions, including more systematic use of the Regional Medical Library network as a field force, to promote understanding and use of NLM's products and services. Implementation of the Panel's recommendations, will ensure more rapid progress in increasing the number of health professionals with direct access to NLM's system.

OUTREACH

Question. Dr. Lindberg, last year the Committee requested that the Library develop an active outreach program to disperse up-to-date biomedical information to rural and remote health care professionals. In response to this request, I understand that the Library convened a panel of experts to assist the Library in expanding and strengthening its outreach activities. What specifically do you intend to do in fiscal year 1990 to meet the goal of getting up-to-date biomedical information out to health care professionals in rural and remote areas?

Answer. At the President's FY 1990 budget level, NLM will be able to continue and increase modestly the following efforts designed to get up-to-date biomedical information out to health care professionals in rural and remote areas:

- Exhibit, demonstrate, and participate in seminars describing direct use of NLM's online information services at meetings of national professional associations (e.g., the Rural Health Association) and local associations likely to be frequented by rural practitioners and health services administrators.

- Direct Regional Medical Library (RML) programs in West Virginia and the Pacific Northwest to travel through remote rural areas demonstrating NLM online services to individual health professionals and show them how to gain direct access to these services.

- Promote the use of DOCLINE, NLM's automated inter-library loan request and routing system, for quick referral of requests for materials not available in small rural hospital libraries to larger libraries that own the materials.

- Promote the use of telefacsimile transfer to get requested items to remote areas more quickly.

- Distribute GRATEFUL MED brochures, order forms, and online application packets through the VA Hospital system and RML network member libraries in remote areas.

With respect to the recently established Board of Regents' Outreach Planning Panel, the Panel has formulated a plan to guide the Library's efforts to improve access to its information services by every American health professional in all settings including remote and rural areas. NLM proposes to begin to carry out the Panel's recommendations. These recommendations include:

- Enhance individual and the Regional Medical Library (RML) Network to bring biomedical information resources within easy reach of all health professionals, especially those individuals in areas that do not currently have direct access.

- Facilitate and strengthen hospital access to national biomedical information sources via the award of

extramural resource "Access" grants and Integrated Academic Information Management Systems grants; and biomedical participation in National Science Foundation Network developments and advanced electronic communications networks.

- o Enhance training in health information management via support for medical informatics training centers, individual awards for research training and career development, and demonstration grants.

- o Expand and enhance intramural research and development programs to ensure a continuous "product line" of improved information products and services and the creation of new systems that are responsive to the needs of the Nation's health professionals.

- o Monitor continuously the actual use of NLM products and services at the levels of individual health practitioner, student, and researcher. Using these data, NLM should mount a national campaign to increase awareness of its information products and services among all health professionals in all settings, and put in place permanent feedback mechanisms to ensure their optimal utility.

As a first step in implementing these recommendations, the Library has just completed a survey of rural health professionals in the state of North Dakota carried out by Dr. Kevin Fickenscher and his colleagues at the Center for Rural Health Services, Policy and Research. This study, a prototype that can be used in other rural settings, describes the information practices and needs of health care providers who frequently are called upon to practice in situations far removed from access to medical library services. The study establishes important baseline data for assessing the impact of outreach intervention strategies with this important population of potential users.

AIDS DATABASE

Question. I understand that the Library has established a new AIDS database that indexes over 13,000 scientific articles on AIDS. As the AIDS field is changing fast with an ever increasing amount of new research, how often do you update the database?

Answer. NLM updates the AIDSLINE database three times each month. Entries are currently increasing at a rate of approximately 500 per month. Over 1,400 individuals and institutions currently subscribe to the NLM AIDS Bibliography.

LIBRARY OPERATIONS

Question. One of NLM's major charges is to acquire and preserve the world's biomedical literature. The fiscal 1990 request includes an add-on of $683,000 for literature acquisition. The volume of the world's biomedical literature grows monthly. Clearly you can't and probably don't want to acquire and index all the literature that is available. How do you select what will be included in the Library?

Answer. NLM staff select literature for the Library's collection according to the selection and acquisition policy adopted by the NLM Board of Regents and the specific written guidelines in the Collection Development Manual of the National Library of Medicine. Revised periodically with the advice of experts in medicine and biomedical research, the Collection Development Manual defines the "scope," or the range of subjects to be acquired, and the "coverage" or the extent to which each subject is to be acquired for the NLM collection. In general, NLM acquires materials directed toward health professionals, broadly defined, and biomedical researchers and does not acquire materials directed toward the general public. Coverage of the scholarly biomedical literature is comprehensive. Certain subjects identified as closely related to biomedicine, e.g., anthropology, zoology, are collected at a level sufficient to support research activity, but selections are limited to English and a few selected foreign languages. NLM maintains only a basic information collection in subjects more peripherally related to medicine. NLM cooperates with the Library of Congress and the National Agricultural Library to keep overlap among the three collections to the minimum necessary to serve their diverse user populations.

NLM indexes only a subset of the journals acquired for the NLM collection. An NIH-chartered Advisory Committee, the Literature Selection Technical Review Committee, assists the Library by reviewing and ranking journals based on their indexability, importance to the field, and quality. NLM takes into consideration the committees' recommendations when selecting journals to be indexed.

CATALOGING BACKLOG

Question. Do you have a backlog in cataloging and indexing new materials?

Answer. At the close of FY 1988, NLM had a cataloging backlog of 9,362 foreign language books, down from 13,301 books at the end of FY 1987. During FY 1988, the Library eliminated the backlog of English language books and reduced the foreign language backlog through a combination of in-house cataloging, contracts with the private sector, and an interagency agreement with the Library of Congress for assistance with foreign language titles for which NLM lacks expertise. If cataloging staffing remains steady and we are able to continue arrangements for outside cataloging assistance, we expect to continue slow reduction of the backlog of uncataloged books.

In early 1989, the backlog of unindexed articles reached a high of about 22,000, or close to one month's production. Although NLM has been able to reduce this backlog, efforts to expand the Library's indexing coverage of the literature of AIDS and biotechnology, and of journals useful to practitioners will continue to lead to periodic indexing backlogs.

SPACE -- PROPER SHELVING

Question. What space problem are you facing?

Answer. NLM has developed a long-range stack plan that assures proper shelving of current and incoming materials through the year 2005. This plan is predicated upon the purchase of an additional 24 sections of compact shelving for the lower two levels of the building over the next 12 to 14 years. The next purchase of compact shelving is scheduled for FY 1992.

Before the Library reaches its full capacity for storing materials in 2005, NLM will have to consider the use of off-site storage and/or the discard of brittle, less artifactually valuable materials that have been microfilmed.

SYSTEM USERS -- HEALTH PROFESSIONALS

Question. GRATEFUL MED is the first widely useful product of your research on developing a unified medical language system. Do you have any idea what proportion of the medical community is accessing the system?

Answer. Although only 2 to 3 percent of the practicing physicians are directly accessing NLM information systems via GRATEFUL MED, many of them acquire information via their library. Approximately 50 percent of the 3 million searches performed per year on NLM systems are for patient care. GRATEFUL MED provides users easy access to MEDLINE and other NLM online files which can also be searched by other mechanisms. The NLM user community's response to GRATEFUL MED is phenomenal. Since its inception in 1986, 14,848 copies of GRATEFUL MED have been sold.

Many members of the medical community use NLM's databases with the assistance of medical librarians or access them on the various vendor and university systems that lease NLM data. Unfortunately, there are no accurate statistics on the numbers of health professionals and researchers using NLM's databases via these mechanisms.

Question. Do you know what proportion of practicing physicians have access to a personal computer in their offices?

Answer. There are no definitive data on the proportion of practicing physicians with access to a personal computer in the office. However, based on data collected by the American Medical Association from a limited sample of U.S. physicians in 1987, the projected estimate is 40-50 percent.

PUBLICIZING PRODUCTS AND SERVICES

Question. How are you advertising the existence and ease of use of the system?

Answer. GRATEFUL MED is being advertised through a variety of means including:

- o Exhibits and Training Seminars at Health Professional Meetings

  With assistance from the Regional Medical Libraries, NLM is mounting an expanded program of GRATEFUL MED demonstrations and training sessions at both national

and local meetings of health professionals. Emphasis is being placed on organizations, such as the Rural Health Association, which include health professionals working in areas where access to information resources is limited.

- Distribution of Brochures, Order Forms, and Online Application Packets through Health Sciences Libraries

  Special posters including GRATEFUL MED brochures and order forms are being developed for use in U.S. health sciences libraries. NLM made special arrangements for distribution of brochures and order forms through all libraries in the Veterans Administration Hospital System.

- Direct Mailings to Health Professionals known to have Personal Computers

- Development of GRATEFUL MED Training Courses and Materials

  GRATEFUL MED instruction is already offered at many medical libraries and health professional schools. NLM is encouraging the continuation and expansion of these efforts by developing training materials and conducting training sessions for medical librarians or health professionals who would like to provide this training.

- Published articles about GRATEFUL MED and its features in a variety of professional journals.

The Library will evaluate the effectiveness of these various activities and modify its approach accordingly.

UNIFIED MEDICAL LANGUAGE SYSTEM

Question. What additional developments from the unified medical language system do you anticipate adding to make your databases even more accessible?

Answer. Additional Unified Medical Language System developments which are currently making NLM's databases even more useful and accessible include the expansion of the Library's Medical Subject Headings (MeSH) vocabulary to provide better coverage of terminology in such fields as cancer, biotechnology, health care technology, epidemiology, ethics, and AIDS; working links between expert systems such as AI/RHEUM and the University of Pittsburgh's QMR/Internist and MEDLINE; and the inclusion of relevant Molecular Sequence Databank record numbers in MEDLINE citations to the biotechnology literature. In 1990, NLM will issue the first version of the UMLS Metathesaurus, which will establish relationships among terminology in several different vocabularies. This new knowledge source will support the development of more powerful user interfaces that can retrieve relevant information from a variety of different machine-readable biomedical information sources.

NATIONAL CENTER FOR BIOTECHNOLOGY

Question. NLM administers the recently established National Center for Biotechnology Information, and is responsible for coordinating a major initiative aimed at improving databases and resource information in biotechnology. NLM was appropriated $7.9 million for these efforts in FY'89 and has requested $8.2 million for FY'90. What is the status of activities initiated to address the computer database and repository system inadequacies associated with analyzing, recording, and retrieving genetic information?

Answer. Commonly cited difficulties with the sequence databases include lack of convenient online access, an absence of integrated analytic software, and insufficient cross-linkages among related databases. Current NCBI projects are addressing each of these areas. The National Center for Biotechnology Information is collaborating on a variety of specific projects with the major molecular sequence databases (GenBank and the Protein Identification Resource); coordinating Center efforts with the Human Genome Office (NIH); and serving the NIH laboratory community by providing online access to sixteen of the key sequence and factual databases. Later this year, the Center will be demonstrating the first computational tools as part of its "molecular biology toolkit", a software design approach that will provide researchers with a visual interface to database and analytic software. The Library is working with GenBank, the Protein Identification Resource, and the Brookhaven National Laboratory protein structure database, to provide biologists with integrated views of the information stored in these databases. To facilitate cross-database searching, NLM's Medline has added a new field in over 12,000 citations which contain sequence data in order to direct users to the appropriate record in one of the sequence databases.

The Center is also providing support to improve access to the Protein Identification Resource through nationwide computer networks.

BIOTECHNOLOGY CENTER COLLABORATIVE EFFORTS

Question. What collaborative efforts are in progress between other Federal agencies and the private sector?

Answer. The National Center for Biotechnology Information is collaborating with and providing support to the database group at the Los Alamos National Laboratories on a variety of projects involving GenBank, and with the Protein Structure database at Brookhaven National Laboratory. The Center is also collaborating with Goddard Space Flight Center in the development of interface software for scientific workstation applications. There are also collaborative efforts underway with the National Agricultural Library on joint acquisition and indexing policies for molecular sequence data. Discussions and joint meetings with the Patent Office have produced plans for making nearly 5000 patented sequences readily accessible to researchers. The National Library of Medicine has coordinated a planning effort involving eight federal agencies for developing specifications for a database of environmental release of genetically-engineered organisms.

With regard to the private sector, the Library has a contract with the American Type Culture Collection to develop and maintain a database of biotechnology information resources. A project with the National Biomedical Research Foundation has been funded by contract to relate the NLM's MeSH indexing vocabulary to the nomenclature used in the Protein Identification Resource sequence database.

VOLUMINOUS GENETIC INFORMATION

Question. Have improvements during the past year helped reduce the problem reported last year that genetic data accumulate at a pace too great to be supported by database and repository systems?

Answer. Although there has been some improvement in the currency of a number of these databases, further progress is still necessary. The Library is currently assisting GenBank, the Protein Identification Resource, and the Human Gene Mapping Library with bibliographic surveillance of the sequence and genetic literature, as well as providing support to the Protein Identification Resource for improved access to nationwide computer networks. A critical need still remains to provide fast, convenient, and powerful access to all the data that are stored. The software development projects in the Center are now addressing this need. Finally, the Center is examining alternative approaches to extracting the critical data elements from the literature in order to build a "backbone" of core biological sequence information that would be up-to-date, comprehensive, and readily accessible.

BIOTECHNOLOGY COLLABORATION

Question. Please discuss the interaction of the NLM program with biotechnology activities in other Institutes of the NIH and with other Federal agencies.

Answer. The NLM program coordinates on both a technical and administrative level with funding agencies of the major databases and with the database developers. Within the NIH, NLM closely coordinates with the National Institute of General Medical Sciences and the Division of Research Resources on activities involving extramural support of molecular biology computing programs. Currently, NLM is providing support to GenBank and Protein Identification Resource projects. These resources will facilitate the interconnection of databases through nomenclature standardization and the use of national research networks. NLM anticipates a similar effort with the Brookhaven protein structure database. The Library participates in a joint committee with representatives from National Institute of General Medical Sciences, the Human Genome Office, Department of Energy, National Science Foundation, and the Howard Hughes Medical Institute for organizing workshops on genetic and physical mapping databases. In cooperation with the National Science Foundation, NLM has organized a series of three workshops on E. coli databases. In addition, we have been consulting on informatics and computational issues with the NIH Office of Human Genome Research, and with the NIH Human Genome Advisory Board.

LONG RANGE PLAN

Question. In reference to the Long Range Plan formulated and recently updated by your Board of Regents, which challenges will be the most difficult to address?

Answer. The Long Range Plan contains a number of initiatives that are very challenging to NLM. Among those initiatives are biotechnology, outreach, unified medical language systems, electronic imaging, and training in health information management.

Biotechnology. The Long Range Planning Panel recommended that NLM initiate a National Biotechnology Information Center. The ability to modify DNA, the molecular blueprint of life, is a central focus in the field of biotechnology. New laboratory methods and equipment for analyzing and changing biologically important molecules such as DNA, RNA and proteins have led to an explosion of new information in the field of molecular biology. This rapid increase in information was outpacing the current systems for acquiring, storing, and disseminating this data in electronic format.

The National Center for Biotechnology Information has now been established as a division of NLM. A major challenge to the Center is to exercise a lead role in the coordination and direction of the information science aspects of database design and development in the field of molecular biology. In addition, NLM must determine how best to distribute that information to the public and, particularly, to the biomedical community.

NLM will have to extend support of new databases to meet newly identified requirements of molecular biology researchers and initiate new information science research projects. Also, workshops and short courses to train researchers on these new information systems will have to be developed.

Outreach. The Board of Regents' updated Long Range Plan places greater emphasis on outreach in an effort to assist NLM in responding to a recent Congressional mandate. That mandate directs NLM to publicize the availability of its products and services, and to develop an active outreach program.

Recently, the Board of Regents convened a planning panel on outreach to guide the Library's efforts to improve access to its information services by every American health professional in all settings. This plan presents many challenges:

- Enhance the individual and the Regional Medical Library (RML) Network to act as a "field force" for NLM products and services.
- Strengthen and facilitate hospital access to information resources.
- Enhance training in health information management.
- Develop new and/or improved products and services to effectively respond to specific needs at the individ-

ual health practitioner, student and researcher levels.

Unified Medical Language System (UMLS). The Long Range Planning Panel recognizes that a fundamental barrier to improved access to biomedical information is the disparity in the biomedical terminology used to describe related concepts in different machine-readable files. The variety of vocabularies in use prevents practitioners and researchers from integrating relevant biomedical information from separate sources, such as the biomedical literature, clinical records, medical databanks, and expert knowledge bases.

The challenge to NLM is to develop a UMLS to compensate for the dissimilarity in the ways related information is classified in different automated systems. The UMLS will make the myriad of classifications of medical knowledge invisible to the user; and make it possible to retrieve and integrate related machine-readable information from multiple sources. UMLS will NOT impose a single vocabulary on all systems.

Electronic Imaging Library. The 1987 NLM Long Range Plan included the recommendation that "NLM should thoroughly and systematically investigate the technical requirements for and feasibility of instituting a biomedical images library." Despite major advances in the science and technology of health care, and despite the new challenges to health care, the education of health professionals remains grounded in the past, in methods that preceded the rapid expansion of biomedical knowledge. It is no longer feasible to expect that biomedical professionals will be able to remember, or access in a few textbooks and journals, all of the information required for effective decision-making.

The NLM challenge with regard to information overload is to take advantage of new electronic information technologies in an effort to facilitate learning and to provide easy access to appropriate information sources for the practicing health care professional. Much of this information is in the form of pictures rather than text or numbers. The increasing power and sophistication of computer displays and digital communications provides the basis for considering image libraries based on electronic media.

Training in Health Information Management. The Long Range Plan of NLM's Board of Regents considers medical informatics training and career development to be among the Library's major challenges. There remains too few persons in the biomedical fields who have had training in the use of computer and communications systems. The need for biomedical professionals cross-trained in informatics and for persons from computer and information sciences, and engineering who have had training in the application of these technologies to health problems continues to increase. Even the major university medical centers have found that locating and recruiting senior professionals with this kind of education and training is their greatest obstacle. Training in health information management skills is critical. Schools of the health professions must recognize the need for, and support a career path for, informatics-trained persons in their own institutional settings. NLM's challenge is to expand and enhance training in medical informatics.

DEMAND FOR COPYING NLM MATERIALS

Question. You have several services through which you lend or copy items for other libraries and for health professionals. Are the demands for copying of journal articles increasing?

Answer. In FY 1988, NLM received 204,484 interlibrary loan requests, of which approximately 91 percent were for photocopies. The number of interlibrary loan requests increased 43 percent from 1985 to 1988; we expect an additional 8 percent increase in FY 1989.

Onsite patrons use the self-service photocopiers provided in the Library. We estimate that onsite users photocopied 158,000 articles in FY 1988. The number of articles copied by patrons has remained steady for the past two years due to restrictions imposed on the number of volumes onsite users may request from the stacks each day.

Question. Do they threaten to overburden the time, money, and personnel resources you have available?

Answer. The effect of rising demand for documents during a period of reductions in NLM's personnel ceiling has been a degradation in the speed and quality of NLM's interlibrary loan service. To alleviate this problem, NLM contracted out the reshelving of volumes in 1987 and in 1989 will contract out the actual photocopying part of the interlibrary loan process. Additional interlibrary loan activities may be contracted out in FY 1990. As NLM recovers the incremental cost of access to its collection, the photocopying contract will be funded from fees collected for interlibrary loan service. Although these contract actions have helped NLM to maintain its level of services, the NLM cannot support the enhancements in document delivery (such as unrestricted telefacsimile service) that the Library should institute to be more responsive to rural health professionals.

MAINTAINING PHYSICAL INTEGRITY

Question. Do they threaten the physical integrity of the collection in any areas (for example, the bindings of journal sets)?

Answer. NLM's mandate to make the materials in its collection available by photocopying, lending, or other appropriate means is inevitably in conflict with its mandate to preserve these materials. The Library's policies and procedures therefore attempt to strike a balance between preserving the collection and providing access to it.

Several factors minimize the potential risk to the NLM collection encountered in photocopying items for offsite patrons:

- Special procedures restrict handling of very fragile items. Once identified, these volumes are microfilmed; interlibrary loans are then filled by loaning microfilm service copies or making paper copies from the microfilm.

- Over 90 percent of the materials used in any given year are less than 10 years old and are therefore in relatively robust condition.

- Since NLM serves as a backup source of documents for U.S. health sciences libraries in the Regional Medical Library Network, use of its collection is spread among many different journal titles and relatively few titles in the collection are heavily used. For example, in FY 1988 NLM received requests for more than 12,000 different journal titles.

Self-service photocopying of articles by onsite patrons poses a greater threat to the collection than the interlibrary loan photocopying done by NLM staff. This risk has been reduced by the establishment of a limit of ten on the number of volumes each user may request from the NLM stacks per day. Onsite patrons who need more items must use the overnight photocopy service provided by NLM staff. The Library also replaced the self-service copiers available to the public with machines that are less damaging to library materials. NLM is continuing to monitor patron photocopying and may find it necessary to implement additional restrictions in the future.

Question. What is your status in regard to copyright law in filling these requests?

Answer. All photocopy requests submitted by remote users must include a statement indicating compliance with the provisions of the Copyright Law or the Copyright Guidelines. Requests that do not indicate copyright compliance are returned by NLM to the requester. DOCLINE, NLM'S automated document request and routing system, will not allow users to release requests until classification of copyright compliance is given. Onsite patrons who request overnight photocopy service must state either that the request is for personal use within the provisions of the law or that royalties will be paid. All photocopies made by NLM staff for onsite or remote patrons include copyright warnings. Copyright notices are also prominently displayed on all photocopy machines in the Library.

SUBCOMMITTEE RECESS

Senator HARKIN. This afternoon we will convene at 1:30 to hear the rest of the Institutes, and hopefully we will wrap up by 4:30 this afternoon.

Thank you all very much.

[Whereupon, at 12:34 p.m., Monday, May 1, the subcommittee was recessed, to reconvene at 1:30 p.m. the same day.]

(AFTERNOON SESSION, 1:35 P.M., MONDAY, MAY 1, 1989)

The subcommittee reconvened at 1:35 p.m., Hon. Tom Harkin (chairman) presiding.

Present: Senators Harkin, Bumpers, and Reid.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF CLAUDE LENFANT, DIRECTOR

BUDGET REQUEST

Senator HARKIN. The subcommittee will resume the hearing this afternoon with the National Institutes of Health. At this point, we will hear testimony from the 11 remaining Institutes and Centers. Our next panel includes the Heart Institute and the Institutes relating to dental health, diabetes, child health, and the eye.

Dr. Wyngaarden, I appreciate your willingness to return for this afternoon's panels. It is a long day for both of us here. I would like to start this afternoon's session with the Heart, Lung, and Blood Institute. The fiscal year 1990 request for the Heart, Lung, and Blood Institute is $1.082 billion, or $36.6 million or 3.5 percent more than last year.

Dr. Lenfant, we are pleased to have you with us this afternoon. If you would like to make a very brief statement that will permit us time to ask a few questions, please proceed.

Dr. LENFANT. Thank you. In my written statement which will be submitted, I have described the many research opportunities which we have in the Institute. The examples I have given demonstrate that the use of the most modern approaches in biology is providing us with new and important knowledge. But, what I would like to underscore at this moment and in the next couple of minutes is that our success in translating pure research findings into diagnostic and therapeutic practices is benefiting the American people. Indeed, the benefits are to individual health, but they are also to all of us because of a decrease in the health care cost burden. This latter point was very well illustrated in recent articles in the press within the last few weeks. They correctly stated that the adoption of the results of one of our studies concerning heart attack treatment, would save up to $200 million a year in medical costs.

I have mentioned in my statement that the application of an education program on asthma which we are developing can save up to $14 in health care costs for each dollar spent in delivering this education program. The most important benefit of our research efforts is the continued improvement of the health of the American people. Our death rate statistics show a decline of 42 percent for coronary heart disease and 54 percent for strokes since 1972. These

declines are greater among younger people. In addition, because of better treatment resulting from our research, today, many patients who will have a heart attack will recover faster and with no or much less sequelae.

PREPARED STATEMENT

Sadly, I must tell you that not all of our programs are this successful. For instance, the death rates from chronic obstructive pulmonary disease and from asthma have increased 37 percent and 33 percent, respectively, in the last 7 years. However, we have clear research directions and opportunities and, therefore, there are many good prospects that we can reverse these trends in the future. Meanwhile, we plan to intensify the dissemination of what we already know, particularly about asthma, to assure that the public receives the full benefits from our research efforts. Thank you, Mr. Chairman.

[The statement follows:]

STATEMENT OF CLAUDE LENFANT

As in the past, I welcome the opportunity to highlight some recent Institute activities addressed to health issues within the purview of the National Heart, Lung, and Blood Institute. These activities are of national importance not only because they contribute to our understanding and management of illness, but also because they increase public awareness of disease problems and thus contribute to our ultimate goal of disease prevention. This year has been especially noteworthy for the application of diverse, innovative approaches that utilize advanced technologies and fundamental research techniques to elucidate disease processes of the heart, blood vessels, lungs, and blood. In some instances, these approaches will lead to disease prevention as well as disease management.

I wish first to allude to examples of what is virtually an explosion of biomedical interest in, and use of, fundamental scientific approaches. These are opening new frontiers, and biomedical researchers are avidly drawing upon them. But, by its very nature, this type of innovation may not have immediate application, whereas when the goals are realized, the health-related dividends may be enormous. The promise is very great and, in a few instances, has already been fulfilled.

Genetic engineering, although a relatively new approach, already has had an impact with regard to "custom-designed" molecules which are appearing and being tested. One example is an extension of an advance I reported last year; namely, the successful use of new thrombolytic agents to dissolve blood clots in the early stages of heart attack. The recombinant form of a naturally occurring tissue plasminogen activator (rt-PA) had been licensed and successfully used clinically. However, all clot-dissolving drugs can cause bleeding and rt-PA is no exception. Recently, protein engineering has resulted in a variety of molecules that retain and perhaps improve the clot-dissolving qualities but may be safer. For example, investigators have developed a hybrid molecule that includes the clot-dissolving part of rt-PA at one end and an antibody which binds fibrin, a clot component, at the other end. This highly fibrin-specific molecule holds the potential of being more effective with less risk of side effects. The definitive answer as to which one or several of these "designer" molecules are effective and whether they are more effective and/or safer than existing agents awaits more research.

The new tools of molecular biology are also helping us learn more about platelets, which are blood components that play an essential role in clotting. Scientists have reported a major breakthrough in understanding platelet adhesion that has led to a new specific method for the diagnosis of blood clots early in the process. Recent studies have shown that a platelet surface glycoprotein complex, when activated, exposes a new receptor site for adhesive proteins such as fibrinogen. Monoclonal antibodies to this site now have been prepared and used to diagnose platelet activation. This finding is leading to the development of new antithrombotic agents that may be useful in the prevention of thrombosis and such thrombosis-related diseases as heart attack and stroke. The information generated from these basic studies will have a significant clinical impact and is likely to result in

further reductions in mortality and morbidity from cardiovascular diseases.

Molecular genetics is offering a promising approach to the awesome problems presented by the more than four thousand human disorders resulting from genetic defects; such problems account for morbidity or mortality in a relatively large number of individuals. Research approaches to these disorders have been virtually revolutionized within the last ten years with the use of what is called "genetic linkage analysis". This methodology first identifies families in which there is a clear pattern of disease inheritance. It then uses molecular biological techniques to find a genetic marker. Genetic linkage analysis has been successfully used to study a number of single gene defect diseases, of which cystic fibrosis is of particular interest to our Institute. This approach has provided the possibility of developing tests to identify the carrier state in a family member for potential diagnosis of the disease in utero. The problems are even more complex for polygenic diseases such as hypertension, atherosclerosis, and asthma because they are multifactorial. Nevertheless, application of linkage analysis to these problems offers the promise of more fundamental understanding of these disorders.

Of great potential in fundamental research is the recently expanding use of transgenic animals to study physiologic functions of human genes which are introduced into cell lines of lower mammals, often the mouse. Because the human gene is integrated into the genetic material (DNA) and transmitted from generation to generation, it results in stable animal colonies that can then be used to study the physiologic functions of the transferred gene. Of particular interest to our Institute are transgenic mice developed to study the genetic sequences necessary for the expression of the renin gene, which plays a crucial role in the regulation of blood pressure and salt balance. Using these transgenic mice, we are learning the DNA sequences that are responsible for the tissue-specific and hormonal control of the renin gene expression. Of considerable interest are the transgenic mice developed to carry the human gene for alpha-1-antitrypsin deficiency which is associated with inheritance of emphysema in certain families. Transgenic mice also may provide an important new approach in the study of other diseases, such as cystic fibrosis and sickle cell disease. Such research is very useful in the study of the pathogenesis of diseases, and it may lead to new therapeutic regimens.

Because of limited availability of human tissues, especially from patients with rare genetic diseases or pathological conditions, there is a critical need to generate specific types of human cell lines that retain a high degree of cellular differentiation. An approach to developing these cells is to generate cell lines with a limitless capacity for replication in cell culture. One typical area in need of such an approach is the development of cell lines for investigating the cellular defect of cystic fibrosis. Indeed, cystic fibrosis lung cells are in short supply and, when available, do not retain their characteristics long enough in cell culture to permit appropriate study. Hence, the Institute is supporting extensive efforts to immortalize cystic fibrosis cells, thereby enabling them to replicate indefinitely,

while retaining their abnormal properties reflective of the original cystic fibrosis-affected cell.

During the past year, the merging of fundamental and clinical research has received a new impetus through the initiation of new programs that have been of particular interest. One of these is the creation of a new laboratory of cardiac energetics which will benefit from the availability of state-of-the-art equipment to study processes involved in utilization of energy by various tissues, including specifically the heart. Through use of magnetic resonance imaging and magnetic resonance spectroscopy, it will be possible to study, in the living, functioning human heart, many processes previously studied only in vitro, or only in animals. Because these techniques will permit noninvasive human studies, they will provide invaluable information about such matters as blood flow, coronary vessel anatomy, and utilization of metabolic substrates by the heart. Another program is the three centers of research in cystic fibrosis that were recently initiated. These centers will emphasize interactive research on various problems related to the basic defect and functional abnormalities of cystic fibrosis. They will also promote the rapid translation of research findings from basic science into diagnostic and therapeutic practice. Finally, the Institute also began three centers of research in sleep apnea to support multidisciplinary studies that integrate basic sleep research as it relates to the heart and lungs with clinical studies of cardiopulmonary disorders of sleep.

Among the clearest evidence of the success of Institute programs in achieving their goals are the encouraging responses to NHLBI efforts to direct its messages to practicing physicians, other health professionals, and the general public. For example, the Institute is supporting a study to assess the impact on survival from heart attack when early administration of rt-PA is performed by paramedicals compared with conventional rt-PA treatment by physicians in emergency rooms. Another example is the bone marrow program that extends significantly the availability of marrow transplants from unrelated but matched donors for those patients who otherwise could not have a transplant because there is no suitable donor in their family. This treatment is used for patients with leukemias and bone marrow failure. The National Bone Marrow Donor Program is a valuable addition to the Institute's portfolio because it is a resource closely related to our long interest in disorders of the bone marrow and the use of marrow cells and cell products to study and treat a wide range of hematologic problems.

Widely known are the Institute's education programs that began with the National High Blood Pressure Education Program (NHBPEP) and now include comparable efforts relative to cholesterol and blood resources. The NHBPEP has recently issued the Fourth Report of the Joint National Committee on Detection, Education and Treatment of High Blood Pressure. The National Cholesterol Education Program (NCEP), now in its third year, issued a Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. These reports provide ample evidence of what can be done when national leaders work together to resolve important public health problems. The National Blood Resource Education Program (NBREP), launched in 1987, is moving into its implementation phase. In addition to the obvious benefits to

individual health that accrue from these educational efforts are the equally important cost-saving aspects of disease prevention.

Still a major health problem in this country, hospitalizations for asthma have increased fivefold for children and doubled for adults over the last 30 years. In 1985, expenditures for health care associated with asthma exceeded $2.5 billion, and this did not include indirect costs accruing from asthma morbidity. But this dismal picture is not hopeless. There is clear evidence that education programs hold promise of reducing such costs if patients and their families are taught to participate in self-management programs which include their physicians. In a study of previously hospitalized patients who were followed for one year, over $14 in health care costs were saved for every dollar spent delivering the program. Model programs for asthma are being widely disseminated by the Institute and it is anticipated that targeting these programs for groups most likely to benefit will have a favorable impact on health care costs associated with asthma. A potential target for lung disease education is farmers. These individuals may be exposed to harmful dusts that irritate lung tissue and produce allergic or toxic reactions, as well as such gases as ammonia, hydrogen sulfide, and carbon monoxide, which can be life threatening. Educating farmers to adopt better work practices can reduce their risk of death and disability from acute and chronic lung disease.

The activities that I have highlighted exemplify the progress we are making in understanding health and disease. It is our firm belief that the pursuit of fundamental knowledge will lead to better approaches for the diagnosis, treatment, and prevention of heart, lung, and blood diseases. We remain committed to encouraging the application of new and innovative approaches to the conduct of fundamental and clinical science and, thereby, to improving the health of the American people.

Mr. Chairman, the FY 1990 budget request for the National Heart, Lung, and Blood Institute is $1,039,846,000. I will be pleased to answer any questions that you may have.

ASTHMA EDUCATION

Senator HARKIN. It is interesting what you say about asthma. How much has it increased? You said it increased fivefold for children or hospitalizations?

Dr. LENFANT. Yes; hospitalization has increased markedly during the last few years. Not only are the seriousness and the prevalence of the disease increasing today, but also the death rate; the death rate during the last 7 years has increased about 33 percent. In fact, asthma and chronic obstructive lung disease are the only two noncancerous diseases whose death rate is increasing.

Senator HARKIN. The $14 you said are saved is in education programs dealing with asthma?

Dr. LENFANT. Yes, sir; this education program is addressed to what we call self-management. Basically, what we do in this education program is educate families of asthmatic children on how to cope with the disease and take care of the crises which develops in

these children instead of them panicking and calling for the ambulance to take the child to the emergency room. What we have learned is that the immediate care can be given by the family; savings in the health care costs are quite considerable.

COST EFFECTIVENESS OF EDUCATION PROGRAMS

Senator HARKIN. Regarding the death rate from heart disease, obviously you have had a big decline in death from coronary heart disease. A lot of people say as much as 50 percent of this improvement is due to better nutrition, healthier lifestyles. I am sure you agree with me that nutrition has a lot to do with this.

But out of your $1 billion budget, we only have $5 million to $6 million in education programs. Would a greater expenditure for education be a very cost-effective way of reducing, still further, the death rate from heart disease?

Dr. LENFANT. We think so, Mr. Chairman. As you know, our Institute is very much involved in educational programs. We have many and, of course, the major ones are concerned with the risk factors of coronary heart disease: High blood pressure and high blood cholesterol. These programs, we believe, are very cost effective and have done lots of good. I am absolutely convinced that if we could expand these programs, we would have even better benefits.

Senator HARKIN. Are you anticipating directing more than $5 million or $6 million in this area?

Dr. LENFANT. Not really. Within the President's budget, we, in fact, have a reduction of the money which is usually devoted to these programs. Once we have our appropriation, most likely we will have to reprogram some money from other activities in order to sustain the same level of effort. We feel very strongly that if we were to diminish the level of effort in our education program, it would be very counterproductive.

You have to sustain a certain level. If you decrease, then when you start again, it is much more work and much more costly than if you had not cut back.

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Senator HARKIN. I am not certain I understand what chronic constructive pulmonary disease is, but you say the death rate continues to rise, why is that?

Dr. LENFANT. Let me say what chronic obstructive lung disease is. For the air to move from and into your lung, you need to have airways which are open. In chronic obstructive lung disease, the diameter is reduced and, therefore, it is much more difficult to move the air in and out of the lung. That condition develops for many reasons. And one of the most obvious is, in fact, the one that was discussed this morning by Dr. Broder, that is smoking.

As you may recall, Dr. Broder was telling you that lung cancer in women is going to be a much greater problem than breast cancer. This is because more and more women took up smoking years ago, and we are now beginning to see the results of that.

With regard to chronic obstructive lung disease, we do have an increase in men, but that increase is not as great as it is in women.

In fact, it is twice as large in women as it is in men. So smoking is a very significant cause of this condition.

TYPE A BEHAVIOR

Senator HARKIN. What do we know for sure about type A behavior and its relationship to heart disease? There has been a lot in the newspapers about this. I keep reading about if you have type A, you are more susceptible to heart disease.

Dr. LENFANT. There have been considerable debates about whether the mood, the temperament, or the personality is a risk factor for coronary heart disease. I think that today, the answer is yes. Personality is certainly a risk factor. As you know, personalities are divided into type A which is the hyper-type of person and type B which is the person who takes things in a more relaxed fashion and lets them come and go.

However, type A, per se, is not really the risk factor. The risk factor is a subclass of type A, namely, individuals who get angry, who get mad all of the time, and are irritable. That has been found to be a very significant risk factor for coronary heart disease. It can be treated, but it is very difficult, because often, the features of a personality emerge when one is a little bit advanced in life and it makes it much more difficult to reverse this behavior.

Senator HARKIN. Do you know if you modify the behavior, does it lessen the risk?

Dr. LENFANT. Oh, yes; there are some experiments that have been conducted which demonstrated that you can, indeed, successfully change the behavior, and therefore, decrease the risk that is present with regard to coronary heart disease. But these are very difficult treatments, and they take time, and so, it is not something that could be done, say by a national education program.

Senator HARKIN. If you have anything written in layman's terms I might understand it. Would you give me an article or something?

Dr. LENFANT. Yes; certainly. I will send you some material on that.

BUDGET REQUEST AMOUNT

Senator HARKIN. I would like to know more about it. Especially what you found in terms of the type of personalities.

Let me get down for the record, you are asking for how much money?

Dr. LENFANT. Our budget request, not including AIDS, is $1,039,846,000, which represents $32.2 million over last year, not including AIDS.

Senator HARKIN. That is only about a 3-percent increase?

Dr. LENFANT. It is a 3.2-percent increase. I have been talking to you here for 16 minutes and during that time 16 people died from heart attack in the country.

Senator HARKIN. One every minute?

Dr. LENFANT. Yes, sir; and yet, if I had testified 20 years ago, I would have told you that 700,000 people would die during that year from heart attack. Last year it was 550,000. Yet, during these 20 years, the population of the country has increased by quite a few million, and so we really can attest to very significant and impres-

sive achievements. I think that the American people have had a pretty good return for its research investment.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Lenfant. But send that to me if you could find some articles on that type A behavior.

There will be some questions which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Question. Dr. Lenfant, the diseases that are studied by the Heart, Lung and Blood Institute represent 55 percent of the deaths in the United States today, with heart attacks being the number 1 killer resulting in almost 46 percent of all deaths. Progress has been made in reducing the death rate from the various heart diseases. No progress, however, has been made in chronic obstructive pulmonary disease, in fact, the death rate continues to rise. What can you tell the Committee about why it has been so difficult to reverse the increasing death rate from chronic obstructive pulmonary disease?

Answer. Cigarette smoking is the most important risk factor for chronic obstructive pulmonary disease (COPD). Death rates are high because the proportion of the population that smokes has been so high. Persons who are now dying from COPD have smoked for 20, or 30, or more years. If the trend of decreasing prevalence of cigarette smoking continues in this country, the number of deaths from COPD should decrease in the future. In the meantime, because of the insidious nature of the disease many persons with COPD present themselves to physicians at a time when treatment has little effect on its course or mortality.

The Institute is supporting a multicenter study, called the Lung Health Study, which seeks to identify cigarette smokers at high risk for COPD at an early stage and determine whether an intervention program of smoking cessation and use of an inhaled drug, a bronchodilator, can significantly alter the rapid loss of lung function which is the hallmark of this disease. Nearly 6,000 smokers are being studied nationwide at ten clinical centers. The results of this study could have a major impact on use of pulmonary function testing to screen and identify persons at high risk for COPD, reinforce the role of physician counseling in smoking cessation, and establish the role of bronchodilators in altering the course of the disease.

HEART ATTACK TREATMENT

Question. I understand that a recent study found that doctors who treated heart attack patients with the clot-dissolving drug TPA, achieved the same one year survival rate when they followed up the drug treatment with "watchful waiting" as did doctors who automatically rushed TPA patients into angioplasty or other surgery. What is the Heart, Lung, and Blood Institute recommending now about the need for angioplasty or other surgery after treatment with TPA? The more conservative strategy seems to be just as effective and, of course, less costly.

Answer. Strategies for the most effective treatment for heart attack victims require early diagnosis and delivery of treatment. During the early period of heart attack, which is usually caused by a blood clot in a coronary artery, irreversible heart muscle damage begins to occur and there is risk of shock and sudden death. Therefore, it is important that the patient receive prompt medical care so that a correct diagnosis is made and confirmed by an

electrocardiogram interpreted by a trained physician. The patient requires continuous medical observation, and treatment is required for abnormal heart rhythm and early signs of shock. It is urgent that the patient receive early consideration for thrombolytic, that is clot dissolving therapy. To obtain maximum benefit, thrombolytic therapy should be given early, but only if appropriate indications are present and there are no contraindications such as a history of stroke or uncontrolled hypertension. The choice of thrombolytic agent is uncertain at the present time, but additional relevant information is anticipated within the next year. Additional pharmacologic agents including beta blockers such as metoprolol may also benefit certain subgroups of patients, but additional information is needed to clarify the benefits and risks.

The National Heart, Lung, and Blood Institute (NHLBI) recently reported on the benefits and risks of mechanical revascularization, percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft surgery (CABG), following thrombolytic therapy for heart attack. Routine performance of cardiac catheterization and PTCA as an emergency procedure during thrombolytic therapy was shown to be ineffective and potentially harmful; this finding has been confirmed by two independent studies. Furthermore, routine performance of cardiac catheterization and PTCA or CABG one or two days after thrombolytic therapy was shown to provide no benefit in terms of survival and recurrent heart attack in comparison with performance of these procedures only after symptoms recur. Demonstration that PTCA and CABG after heart attack are needed only for recurrent symptoms should result in substantial savings of up to $200 million per year in medical costs.

ARTIFICIAL HEART

Question. Last year there was some controversy over NHLBI continuing work on the artificial heart. I understand that work is continuing on the artificial heart, as well as the left ventricular assist pump. I also understand that a clinical trial is underway on a experimental heart pump no bigger than a pencil eraser that gives the heart a rest. A tiny screw inside the tube inserted into an artery rotates at great speeds, up to 25,000 revolutions per minute, to pump blood through the body at almost the same volume as a normal heart. This is thought to allow the ailing heart to rest and repair itself. What progress is being made on this clinical trial, and could this type of Hemopump replace the need for the development of an artificial heart?

Answer. The hemopump consists of a miniature propeller attached to a miniature electric motor, which runs at 25,000 rpms, all contained within a catheter that can be feed into the heart through an incision in the skin and a selected blood vessel. During the past 12 months, 35 patients with cardiogenic shock have been treated for as long as seven days with the hemopump. These patients were considered to be in a preterminal state with little likelihood of survival on conventional treatment. Preliminary information suggests that survival may have been improved over that expected with conventional treatment. Some of these patients have responded dramatically with prompt return of consciousness and with recovery of heart function and subsequent return to home and work. No serious complications such as heart valve damage, stroke, or

other embolic events attributable to the catheter system and pump have been reported. No definitive data are available for direct comparison of outcome with alternative treatments.

If these results are confirmed with additional studies, this device could become an important addition to the short-term treatment of acute, catastrophic heart failure. Cardiogenic shock continues to be responsible for most in-hospital deaths from heart attack, and there is a need for more effective treatment.

This type of hemopump does not replace the need for development of an implantable artificial heart. The hemopump is designed to provide resting level circulatory requirements for a few days, or possibly in the future, a few weeks, as the patient recovers or moves to a second procedure. The implantable artificial hearts under development are being designed to assume the full workload of the heart, while at rest or during moderate exercise, for at least five years of uninterrupted operation.

HEART ATTACK TREATMENT

Question. I understand that the relatively new drug, TPA, has been successful in treating people suffering from heart diseases and heart attacks, but that the timing in the use of the drug is crucial. I was told that the drug has only been effective if the infusion was begun within a few hours of the start of a heart attack. In view of the importance of timeliness in the use of TPA, and other interventions when people are suffering heart attacks, I was curious about a clinical trial you now have underway testing the effectiveness of early treatment by ambulance crews as opposed to postponing treatment until the patient is delivered to the emergency room and treated by hospital staff. What do you really expect to learn from this clinical trial regarding the importance of the timely application of TPA and other treatments to heart attack victims?

Answer. Thrombolytic therapy is associated with bleeding complications which can be serious, especially in patients with cerebrovascular disease, uncontrolled hypertension, or other associated conditions in which there is increased risk for hemorrhage. Some acute illnesses mimic the symptoms of heart attack or may be associated with a heart attack, but have underlying pathology which predisposes to catastrophic hemorrhage. These include acute aortic dissection, pericarditis, and gastrointestinal ulcer. Another aspect of the problems to be faced in providing rapid diagnosis and treatment for heart attack is the high frequency of relatively benign conditions which mimic the symptoms of heart attack; such patients should not be exposed to the real risks of thrombolytic therapy. While it is important to deliver thrombolytic therapy early, it is more important first to make the correct diagnosis and to rule out associated diseases which contraindicate thrombolytic therapy.

Question. Don't we already know that early treatment is desirable even crucial?

Answer. The NHLBI is supporting a clinical trial to determine whether thrombolytic therapy can be provided safely and effectively

by specially trained ambulance crews who are in direct contact with a physician at a medical center. Before treatment is started, the physician reviews the electrocardiogram, which is transmitted by telephone, to confirm the diagnosis of acute myocardial infarction. Patients are randomized to receive thrombolytic therapy by the ambulance crew in the field or to be taken to the emergency room of the closest hospital for confirmation of the diagnosis and treatment as indicated.

If this study shows that thrombolytic therapy given by specially trained ambulance crews under the remote supervision of a physician is safe and results in better clinical outcome, then it will be important to disseminate this practice. Given the potential for incorrect evaluation outside of the hospital setting and for serious complications with inappropriate treatment, it is our judgement that the use of thrombolytic therapy by ambulance crews should be deferred until the safety and efficacy of such treatment can be established.

CYSTIC FIBROSIS

Question. Last year, the committee provided the National Heart, Lung and Blood Institute with $500,000 and the Diabetes Institute with $2.5 million to establish cystic fibrosis centers. I understand that NHLBI was able to establish 3 centers by reprogramming some funds to complement the allowance made by the committee. One of these new centers was awarded to the University of Iowa and these centers, I understand, are doing basic research in identifying the gene responsible for cystic fibrosis. What can you tell us about progress being made to identify that gene?

Answer. Research toward identifying the gene responsible for cystic fibrosis (CF) continues at an exciting and intensive pace. Indeed, several research groups are believed close to a breakthrough. The quest for the CF gene has benefitted greatly from a new technique called "jumping" which has allowed scientists to hop over large pieces of genetic material without having to clone everything in between. Using this technique, scientists can cover five to ten times more genetic material than by using previous methods and have now narrowed the search for the CF gene to approximately 275,000 base pairs, a very narrow range when compared to the 3 billion base pairs that constitute the body's entire genetic material. This fragment, representing less than 1/100 of one percent of the DNA, is thought to contain 6 or 7 genes, one of which is the CF gene. To facilitate this search, scientists at a CF center have devised a unique "fluorescent indicator" system for testing these "candidate" genes in CF cells. Using this system, scientists are assessing candidate genes for their ability to correct the chloride transport defect of CF cells and are optimistic that these new approaches will facilitate efforts to identify the CF gene.

Question. How many cystic fibrosis centers did the Diabetes Institute establish with its allocation of $2.5 million?

Answer. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established one CF research center at Columbia University in 1988.

Question. Since you are apparently more interested in this problem, should we transfer all the cystic fibrosis work to you?

Answer. Cystic fibrosis is a multiorgan disease involving nutritional, digestive, exocrine and pulmonary manifestations. However, pulmonary disease is the primary cause of much of the morbidity and mortality from cystic fibrosis. Because of this, cystic fibrosis is an important program area of both the NIDDK and the NHLBI. Our Institute worked with the NIDDK in developing the solicitation for the cystic fibrosis centers applications, and agreed in advance on the kinds of applications that would be assigned to each of the Institutes. The applications assigned to NHLBI were more successful. We are pleased to be supporting these very visible research programs in this important research area.

GENE TRANSFER STUDY

Question. I understand that the Food and Drug Administration gave approval for an experiment being conducted by intramural scientists at NIH, including Dr. Anderson of the NHLBI, to transfer genes into live humans. What can you tell us about the progress of this research, and what is the prospect for gene transfers to cure human diseases?

Answer. Intramural research scientists Drs. Anderson, Blaese, and Rosenberg have been approved to carry out the first experiment in which a gene will be inserted into the cells of a human patient. The clinical study will put a "marker" gene into the cancer-fighting immune cells of terminal patients with malignant melanoma. These immune cells are called tumor infiltrating lymphocytes (TIL). The goal is to develop ways to make the TIL more effective in combating advanced cancer. The procedure is to remove TIL cells from a patient, culture the cells in the laboratory, insert the marker gene and then re-introduce the cells into the patient. A number of patients have now been selected and their cells are in ulture. It is likely that at least one of these patients will receive gene-marked cells in the next 3 to 6 weeks.

This first experiment is designed to gain knowledge to help in the treatment of cancer; specifically, to improve the effectiveness of TIL immunotherapy. It will not directly help the patients in the study. In the future, however, it ought to be possible to develop treatments for what are now incurable diseases. The diseases now under active investigation for possible treatment by gene transfer are: cancer, AIDS, heart diseases, and genetic diseases.

CARDIAC ENERGETICS

Question. The Heart, Lung, and Blood Institute spent $3.5 million to develop a laboratory of cardiac energetics. I understand that this will permit the acquisition and installation of a unique, very large magnetic resonance instrument. Is this new equipment now in operation, and could you tell the committee the benefits you expect from experiments with this new cardiac energetics technology?

Answer. The instrument you are referring to is a high field magnetic resonance instrument for studies on human subjects. The instrument and the facility to house it are currently in the final stages of bidding and negotiations with an award date set for the end of June. The timetable for constructing the facility and assembling the magnet, as well as peripheral electronics is twelve months from the date of award. Therefore, we are anticipating a fully operational facility in June of 1990. The Laboratory of Cardiac Energetics staff is already actively developing the hardware and software for this program using the smaller systems currently available to them.

This instrument will permit non-invasive investigation of the function, structure and biochemistry of the human heart at the highest magnetic field strength available in the appropriate dimensions to study the human body. This magnetic field is forty thousand times the earth's magnetic field. This instrument will provide unique insights into the biochemistry and structure of the human heart with the ultimate goal of developing new strategies in the diagnosis and treatment of heart disease. Specifically, the high signal-to-noise characteristics of this instrument will permit the acquisition of high resolution movies of the heart action, blood flow and cardiac valve motion. This high magnetic field will also permit the monitoring of the intracellular metabolites involved in the distribution of energy in the heart. These data will provide information on the metabolism of the human heart and shows promise as a diagnostic tool. We will also be investigating other organ systems in collaboration with other research groups at the NIH and around the country. These investigations will include studies on the human brain, kidney, liver and skeletal muscle. Working together with other clinical branches at the NIH, we have already begun to develop the clinical protocols to take advantage of this new technology. Our first efforts will be to characterize normal human cardiac function and metabolism and investigate various forms of ischemic heart disease.

RESEARCH CONTRACTS

Question. Your Institute has agreed to continue the National Bone Marrow Donor Program and to develop the total artificial heart. I believe both these programs are supported by research contracts. Since there is a reduction for research contracts, as proposed in your budget, are there sufficient funds to continue these programs?

Answer. Although we will not curtail any ongoing contracts because of the FY 1990 President's Budget, we will have to very carefully review each contract to see if cost savings are possible. If we are not able to identify savings in contracts, we will request a reprogramming of funds from another source. There are sufficient funds in our FY 1990 budget to continue these two contract programs.

ARTIFICIAL HEART PROGRAM

Question. What is the current status of the artificial heart research program?

Answer. The goal of the artificial heart research program is to develop mechanical support devices to rehabilitate patients with end-stage heart disease, including the development of circulatory assist and total heart replacement devices for temporary and permanent support of the circulation. Currently, the Institute is completing the Device Readiness Testing Program for implantable electrically powered left ventricular assist systems, which will be followed by clinical testing in patients. In FY 1988, the Institute began a program to develop tether-free, implantable, electromechanical actuated artificial heart systems to support patients with end-stage heart disease. This program continues.

Question. How much is currently being spent on this research by NHLBI?

Answer. In FY 1989, the Institute plans to spend approximately $10.5 million on the circulatory assist program. We expect to spend approximately $13.0 million in FY 1990.

Question. How does this compare to previous years?

Answer. In previous years $8.5 million was spent in FY 1987 and $15.2 million was spent in FY 1988.

Question. What recent developments have occurred that may improve the viability of this technology either as a bridge to transplantation or as a more permanent alternative for patients with a failing heart?

Answer. Two developments have occurred which suggest improved viability for artificial heart technology. Recently two patients, one 45 years old and the other 39 years old, with complex tissue matching requirements were successfully bridged to cardiac transplant after 125 and 132 days of ventricular assistance with an implanted device. The patients exercised regularly and the heart performed effectively after implant of the device. This result is significant because this is the longest that devices specifically designed for chronic human use have been implanted in patients and the length of these implants exceeds the 112 days that Dr. Barney Clark lived with the first artificial heart implant.

The second development is the introduction of two new temporary ventricular assist systems for bridge to transplant into FDA regulated investigative device exemption trials. The expertise and experience necessary for developing these devices evolved from NHLBI funded grants and contracts. These systems appear to be as safe and effective as the devices that are currently used but they are much less costly. Current systems average $10,000 to $20,000 per patient, while the newer systems will cost $3,000 to $6,000 per patient.

Question. How long is the current program to last?

Answer. The electrically powered, implantable artificial heart program is scheduled to continue through September 1993. This is a research and development program which allows for new innovation based on the lessons learned from our other grant and contract programs. All four contracts have completed their basic design and

two of the four contractors will soon have animal prototype versions for testing. The program was initiated in January 1988.

Clinical evaluation of an implantable, electrically powered ventricular assist system is scheduled to begin in 1991 and will continue through May 1995. The system will be implanted in patients with severe, medically intractable heart failure. We are soliciting proposals for two Clinical Centers and a Clinical Coordinating Center to evaluate these systems in twenty carefully selected patients.

PROGRAMS OF EXCELLENCE IN MOLECULAR BIOLOGY

Question. The Program of Excellence in Molecular Biology was created to promote interdisciplinary investigations in molecular biology research with basic research in heart, blood, and lung, and strengthen the field by training new investigators. How many investigators are engaged in this research effort?

Answer. Currently, there are two Programs of Excellence in Molecular Biology. The one at the Massachusetts Institute of Technology consists of eight senior investigators, and the one at the University of Cincinnati consists of ten senior investigators.

Question. What is this program costing?

Answer. Funds for a Program of Excellence in Molecular Biology are used to provide supplies and equipment to support new research initiatives, establish core facilities that provide services for these research efforts, to support investigators and technical help, and to develop skills of future, independent investigators. The total costs for the two grants in FY 1989 are $3,948,340.

Question. How many new investigators are being trained under this program?

Answer. These two programs were established September 30, 1988. The University of Cincinnati has currently enrolled nine individuals, and will have twenty by the end of September, 1989. MIT has enrolled ten individuals, and will have sixteen by the end of September, 1989.

Question. What types of similar programs exist or are being initiated in other Institutes, and, if so, what type of coordination is planned?

Answer. This program is unique in its combination of features and goals. While other Institutes have programs of excellence or centers of excellence, these programs are tailored to specific goals and have specific features depending upon the needs within an individual Institute. The Deputy Director for Extramural Research, NIH, coordinates any policy issues that are raised by particular features which characterize one or more of these programs.

TREATMENT OF EMPHYSEMA

Question. In the many areas of research concerned with adult lung disease (which is increasing), how close are we to providing AAT (alpha-1-antitrypsin) as general treatment to the two million Americans suffering from emphysema?

Answer. Alpha-1-antitrypsin (AAT) was approved by the FDA in January 1988 for use only in patients who suffer from familial emphysema due to a genetic deficiency of AAT in their serum. Only about two percent of the cases of emphysema (about 40,000) are due primarily to this genetic deficiency; the major cause of emphysema in most cases is cigarette smoking. Alpha-1-antitrypsin augmentation therapy is not an effective treatment for those individuals who suffer from emphysema due to cigarette smoking. In fact, even in patients with the genetic deficiency, augmentation therapy with AAT can only prevent the progression of emphysema and stabilize the lung function; it can not reverse existing emphysematous lesions.

Research investigations continue to try to find an effective treatment for the non-familial form of emphysema, or the smoker's emphysema. It has been demonstrated that cigarette smoking causes a complex cascade of biochemical mechanisms initiated in the lung by cigarette smoking. Localized inactivation of AAT in the lungs by cigarette smoke constituents is believed to be one of these mechanisms. However, there is no significant decrease in the overall concentration of AAT in the lung tissue and there is no reduction in the serum levels of the protein in these patients. Moreover, the localized deficiency of AAT in the lung is believed to revert to normal levels on cessation of cigarette smoking. Thus, at present there is no biochemical or clinical evidence to indicate that providing the AAT augmentation therapy to emphysema patients, who do not have the genetic deficiency of AAT, will be beneficial. Since at present there is no cure for emphysema, cessation of cigarette smoking, especially at an early stage, is the best treatment for such patients.

ADULT RESPIRATORY DISTRESS SYNDROME

Question. What, if any, treatment relationship has come out of the research concerned with adult respiratory distress syndrome and tumor necrosis factor?

Answer. Recent studies in animals have provided evidence that tumor necrosis factor (TNF) is a mediator of acute lung injury. TNF is a protein produced by white blood cells in response to inflammatory stimuli. It stimulates white blood cells to produce toxic molecules which kill tumor cells and bacteria. It is thought that through similar mechanisms white blood cells are pathologically induced to attack lung cells. From basic studies of these events in cell culture and in animals, investigators hope to better understand how TNF causes injury to the lung.

If TNF proves to be a key mediator of the acute lung injury associated with adult respiratory distress syndrome, new therapies could evolve, including the development of special monoclonal antibodies to neutralize TNF in the lung, development of agents

that will prevent the binding of TNF to the cell's surface, and development of inhibitor molecules that will block the release of toxic molecules.

ASTHMA

Question. What types of educational programs might be initiated in the area of lung disease in order to stem the tide of this increasing public health problem?

Answer. Asthma is a major public health problem affecting more than 15 million children and adults in the United States. Both mortality and hospitalizations for asthma are increasing. Those who suffer from this disease often need to avoid precipitants of attacks, take continuous medication, use medical care appropriately, and perhaps change lifestyle or livelihood. This year, the National Heart, Lung and Blood Institute began to develop the National Asthma Education Program to: raise awareness of patients, health professionals and the public that asthma is a serious chronic disease; ensure the recognition of the symptoms of asthma by patients, families, and the public, and the appropriate diagnosis by health professionals; and ensure effective control of asthma by encouraging partnership among patients, physicians, and other health professionals through modern treatment and education programs. Through this National Asthma Education Program, activities of at least 21 organizations will be coordinated to assure a broad based program which reaches millions of children and adults with asthma.

Demonstration research projects targeted to populations of children with asthma have shown the benefits of asthma self-management programs by reduced absences from school, decreased symptoms of asthma, improved control of the disease, and reduced hospitalizations. Similar research programs are now addressing the needs of adult asthmatics, and model strategies are being developed in several research laboratories. However, additional research is needed to determine the most effective ways to reach minority populations in both rural and urban settings, as data indicates that both morbidity and mortality rates for asthma in these populations are significantly higher than rates in the white populations. The Institute is planning to announce a special initiative to investigate methods to reach the high risk populations of asthmatics and to provide educational programs for management of their disease.

NATIONAL CHOLESTEROL EDUCATION PROGRAM

Question. In 1985, NHLBI launched the National Cholesterol Awareness Program, can you tell us how long this program is expected to run?

Answer. The National Cholesterol Education Program was launched in November 1985 to reduce the prevalence of high blood cholesterol in the United States through a concerted program of professional and public education. Like high blood pressure, high blood cholesterol is a major modifiable risk factor for coronary heart disease that affects roughly 60 million Americans. Millions more have blood cholesterol levels that are higher than desirable.

Experience with the very successful effort to control high blood pressure, which has been coordinated by the NHLBI for the past 16 years, has shown that a strong Federal role is essential for dealing with a risk factor of this magnitude. Although gratifying progress is being made in the campaign to reduce blood cholesterol levels, a strong leadership role by the NHLBI will be needed for the foreseeable future.

Question. How much will the Federal component of this program cost, both in total funding and on an annual basis?

Answer. The Federal component of this program serves as a catalyst to very substantial cholesterol education efforts by the private sector. In order to carry out this function, the NHLBI convenes expert panels to deal with scientific issues, produces educational materials for professionals and the public, and conducts a mass media campaign that encourages the public to know their cholesterol levels. Many of the activities related to cholesterol education are part of larger efforts directed also to other risk factors such as smoking and high blood pressure. Thus, a single contract provides staff support for cholesterol, smoking, high blood pressure, and blood resource education, and a kit of materials and ideas for program planners covers cholesterol, smoking, and high blood pressure. Costs for cholesterol education are thus, not reflected in a single accounting or budget line. Overall, the cost of the NCEP for FY 1989 is approximately $1.3 million for activities directly related to this program, but excluding the cost of activities related to more than one of our education programs.

Question. How successful has the program been to date in making Americans both aware of their cholesterol levels and in helping to reduce individual cholesterol levels?

Answer. The program has been quite successful in making Americans more aware of their cholesterol levels. Data from the FDA show that, from 1983 to 1988, the percent of the public who reported having their cholesterol checked rose from 35 percent to 59 percent, and Gallup poll data from 1989 show that the figure has risen to 66 percent. From 1982 to 1988, patient visits to physicians for hypercholesterolemia went up over 800 percent. We will be better able to assess progress in reducing individual cholesterol levels when a new round of physician and public surveys scheduled for late 1989 is completed, and when the results of NHANES III survey are available. This latter survey will actually measure cholesterol levels.

Question. What is the role of the private sector in implementing this educational effort, and how successful has this cooperative effort been?

Answer. The private sector plays a crucial role in implementing the National Cholesterol Education Program. The program operates as a partnership between the Federal government and the private sector. The coordinating committee for the Program illustrates this point. The Director of the National Heart, Lung, and Blood Institute (NHLBI) serves as chairman of the coordinating committee, and other Federal agencies have liaison representatives to the coordinating committee. The members of the coordinating

committee, however, are almost entirely health and medical organizations in the private sector. These private sector organizations provide advice to the national program about priorities, directions, and strategies, and then implement these program elements through their own activities. Coordinating committee organizations such as the American Heart Association, the American Medical Association, and the American Dietetic Association, all have significant cholesterol education activities. In addition, private companies are contributing through reprinting of program materials and by mounting independent initiatives that lead to greater cholesterol awareness by professionals and the public. The cooperative effort between NHLBI and the private sector has been most successful, and a significant part of the credit for the increased awareness that we are witnessing has to be given to the efforts of the private sector.

Question. How many individuals have been reached by the program to date?

Answer. The program has reached a very substantial portion of the U.S. public. From 1983 to 1988, the percent of the public who were convinced that lowering high blood cholesterol would have a large effect in preventing heart disease rose from 64 percent to 77 percent; the percent who reported having their cholesterol checked rose from 35 percent to 59 percent; and Gallup poll data from 1989 show this figure to be up to 66 percent. From 1982 to 1988, patient visits to physicians for high blood cholesterol rose over 800 percent. Cholesterol is being highlighted almost daily in the press, on television, and on radio. The message is getting through, and we will be tracking various indicators to measure the progress that is being made.

THROMBOLYTIC THERAPY

Question. A number of thrombolytic drugs are now available to limit the damage to the heart muscle following myocardial infarctions, or heart attacks. However, recent controversy surrounding the use of thrombolytic therapy has been concerned with the cost and efficacy of these various agents. What light can you shed on the choice of one thrombolytic agent over another in terms of safety and efficacy?

Answer. Three thrombolytic agents have been approved for treatment of coronary artery thrombus in the setting of acute myocardial infarction. However, there is insufficient information at the present time for adequate comparison of clinical safety and efficacy. The cost of streptokinase (SK) is substantially less than recombinant, tissue-type plasminogen activator (rt-PA), but rt-PA has been shown to dissolve clots quicker than SK. A large clinical trial to compare mortality in patients treated with these two agents is in progress in Europe; results are anticipated in 1990. The third agent, urokinase, approved for intracoronary administration, is also being evaluated for intravenous administration. Other trials are in progress or are planned which will provide additional information about these and other thrombolytic agents or combinations of agents.

Basic and clinical research is in progress to develop safer and more effective thrombolytic therapy in combination with additional treatments to interrupt the process of heart injury and to promote healing and recovery of the involved coronary artery and the heart muscle. Preliminary results from some of these studies indicate that important additional advances are possible. Mortality from acute myocardial infarction has been reduced substantially by first generation thrombolytic agents. Additional progress in this area promises additional reductions in the morbidity and mortality associated with heart attack.

Question. What medical rationale exists for the Health Care Financing Administration to refuse to provide reimbursement for the use of tissue plasminogen activator (tPA), one of these drugs which is expensive because it is produced by genetic engineering?

Answer. Adequate information to compare clinical outcomes among thrombolytic agents is not yet available. A number of studies are currently comparing outcomes in heart attack victims assigned to treatment with rt-PA compared with those assigned to treatment with streptokinase, an older and less expensive agent. Although I am not familiar with the basis for the Health Care Financing Administration decision, there is no definitive evidence at present that one agent is superior to the other relative to long term survival. Results of ongoing studies will be available next year.

Question. What new information exists on the window of opportunity in terms of use of these agents, that is, the critical time period in which they are most effective?

Answer. A number of basic and clinical investigations are in agreement about the importance of early thrombolytic treatment. The earlier the treatment, the greater the benefit. The length of the window of opportunity is less well defined, and this may depend importantly on the clinical manifestations at the time the patient presents for treatment. Thus, if a patient shows evidence of continuing ischemic injury, which is active progression of heart muscle damage, thrombolytic therapy should be considered regardless of the delay. The majority of studies indicate that on the average, benefit is diminished with more than four to six hours delay from the time of symptom onset to the initiation of thrombolytic treatment. However, one large international study showed evidence of benefit up to 24 hours after the onset of symptoms; therefore, this issue is unsettled at the present time. More information is needed about the risks and benefits of thrombolytic treatment after six hours.

Question. What has been learned from the Thrombolysis in Myocardial Infarction II Study concerning subsequent treatment of patients who have received this therapy?

Answer. The Thrombolysis in Myocardial Infarction II study investigated the benefits and risks of invasive treatment that is cardiac catheterization followed by PTCA or CABG after thrombolytic therapy given to heart attack victims within four hours of symptom onset. Patients randomized to the invasive strategy were compared with patients randomized to a conservative strategy of watchful

waiting and performance of cardiac catheterization and PTCA or CABG only if the patient had a recurrence of myocardial ischemia.

The results showed that there is no advantage with routine cardiac catheterization and PTCA or CABG following thrombolytic therapy. Therefore, it may be concluded that angiography and invasive treatment are not needed in all patients during the acute phase of myocardial infarction but can be reserved for patients with developed symptoms and signs of recurrent myocardial ischemia.

BLOOD DISEASES

Question. Related to the several factors identified that can be used to treat various blood disorders, to what extent is erythropoietin being used to treat individuals with the anemia of end-stage renal disease, sickle cell anemia, and Cooley's anemia?

Answer. Over 25 years ago, the NHLBI recognized the central role that erythropoietin plays in the control of red blood cell production and its potential for treating a variety of anemias. As a result, the NHLBI began a program for the isolation, purification, and worldwide distribution of human urinary erythropoietin in an effort to foster research in this important area. NHLBI grantees were instrumental in the efforts to clone the gene and the eventual production of large quantities of the recombinant hormone. This made clinical applications possible, and multicenter clinical trials, supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), are now in progress to determine the efficacy and safety of erythropoietin in the treatment of the anemia of end-stage renal disease.

Erythropoietin has been used in a small number of patients with sickle cell anemia and the results have been mixed. About one patient out of four has responded to treatment with very high doses. We are not aware of any Cooley's anemia patients being treated with erythropoietin. It should be noted that the goal in treating the anemia of renal disease is to increase the mass of normal red blood cells. This is not therapeutically possible in sickle cell anemia and Cooley's anemia because a genetic defect produces an abnormal hemoglobin in the former, and a genetic inability to produce sufficient normal hemoglobin in the latter. The object of erythropoietin therapy in sickle cell and Cooley's anemia patients would be to cause a switch from normal adult hemoglobin synthesis to fetal hemoglobin synthesis. Fetal hemoglobin would substitute for the abnormal sickle hemoglobin in sickle cell anemia or the insufficiently produced normal adult hemoglobin in Cooley's anemia. Erythropoietin is also being used experimentally to treat the anemia resulting from a side effect of azido thymidine (AZT) treatment in AIDS patients. Separate pilot clinical studies are supported by the NHLBI and industry.

Question. What is the current status of the Specialized Centers and the Comprehensive Centers supported by the Blood Diseases and Resources Program, how many are there, and where are they located?

Answer. The Division of Blood Diseases and Resources currently supports three Specialized Centers of Research in Transfusion Medicine, four Specialized Centers of Research in Thrombosis, and ten Comprehensive Sickle Cell Centers. The Centers in Transfusion Medicine, which are currently competing for renewal, will be funded in January of 1991 for a five year period. Centers in Thrombosis are, similarly, in the process of recompetition and will be funded in May of 1991 for five years. The ten Comprehensive Sickle Cell Centers have recently been recompeted and were funded for a five year period beginning in April 1988.

Listed below are the institutions and states where the Specialized and Comprehensive Centers are located:

Specialized Centers of Research in Transfusion Medicine:

1. Center for Blood Research, Boston, Massachusetts
2. Puget Sound Blood Center, Seattle, Washington
3. Stanford University Blood Center, Stanford, California

Specialized Centers of Research in Thrombosis:

1. Washington University, St. Louis, Missouri
2. Cornell University Medical Center, New York, New York
3. University of North Carolina, Chapel Hill, North Carolina
4. University of Vermont, Burlington, Vermont

Comprehensive Sickle Cell Centers:

1. Children's Hospital Research Foundation, Cincinnati, Ohio
2. Boston City Hospital, Boston, Massachusetts
3. University of California, San Francisco General Hospital, San Francisco, California
4. The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
5. Meharry Medical Center, Nashville, Tennessee
6. Columbia University, College of Physicians and Surgeons, New York, New York
7. Duke University Medical Center, Durham, North Carolina
8. Wayne State University School of Medicine, Detroit, Michigan
9. University of South Alabama College of Medicine, Mobile, Alabama
10. Montefiore Hospital Medical Center, Bronx, New York

Question. What is the current status of centers that were set up to research and treat sickle cell anemia, how many are there, where are they located and how long does their competitive renewal last?

Answer. The Comprehensive Sickle Cell Centers program was initiated by the NHLBI in 1972. The last competition was completed in 1988 for a five-year project period. As required by law, ten (10) centers are currently funded. They are located in the following institutions and states:

Comprehensive Sickle Cell Centers:

1. Children's Hospital Research Foundation, Cincinnati, Ohio
2. Boston City Hospital, Boston, Massachusetts

3. University of California, San Francisco General Hospital, San Francisco, California
4. The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
5. Meharry Medical Center, Nashville, Tennessee
6. Columbia University, College of Physicians and Surgeons, New York, New York
7. Duke University Medical Center, Durham, North Carolina
8. Wayne State University School of Medicine, Detroit, Michigan
9. University of South Alabama College of Medicine, Mobile, Alabama
10. Montefiore Hospital Medical Center, Bronx, New York

NATIONAL BLOOD RESOURCE EDUCATION PROGRAM

Question. What is the purpose of the National Blood Resource Education Program started recently and how much is being spent on this effort?

Answer. The National Blood Resource Education Program (NBREP) was launched by the Institute in 1987. The program was established to ensure an adequate supply of safe blood and blood components to meet the Nation's needs, and to ensure that blood and blood components are transfused only when therapeutically appropriate. To accomplish these program goals, the NBREP works with more than 30 national organizations with interests in blood donation, transfusion, and health education for the public and health professionals. The NBREP is a three-pronged educational effort aimed at health professionals, patients, and the general public. Examples of program activities include developing guidelines for the medical community on appropriate indications for using specific blood components as well as on the use of a patient's own blood for transfusion. Public education activities and materials will focus on increasing awareness of the donation process and the risks and benefits of blood transfusion. Educational messages will be aimed at encouraging healthy, eligible blood donors to give blood on a regular basis. The NBREP's cost for FY 1989 is approximately $595,000 for activities directly related to this program, but excluding the cost of activities related to more than one of our education programs.

BASIC RESEARCH

Question. The President's Budget proposes an increase for the basic research program of the National Heart, Lung, and Blood Institute. I see from the mechanism table that the research project grant category and the intramural research category increase while the research center category and research contracts decrease. What happens to the basic research supported by centers and contracts?

Answer. Because the NHLBI's research centers programs are designed so that each individual center includes both basic and clinical research, they constitute an effective mechanism for not only insuring that basic research advances receive rapid application into clinical practice but also that the direction of basic research is guided in part by the needs of clinical practice. Because no particular percentage distribution between clinical and

basic research is required in any given center and it is the responsibility of the principal investigator to adjust the research program as necessitated by the resources available, it is difficult to estimate with great accuracy exactly what reductions will result in the basic research conducted in the NHLBI's research centers programs. However, it is likely that reductions in the basic research conducted by the centers programs will be proportionate to the overall reductions in the research centers category.

Research contracts are used by the NHLBI to acquire research to meet predetermined program needs. Therefore, the Institute relies upon the contract mechanism to support much of its developmental work on methodologies required for effective screening of the blood supply and on biomaterials. It also relies upon the contract mechanism to conduct many of its important epidemiological studies and clinical trials. Epidemiological studies have provided and will continue to provide critical direction to the basic research efforts related to cardiovascular, pulmonary, and hematological diseases. Similarly, clinical trials provide essential feedback on the efficacy of the products of basic research in the prevention, detection, and treatment of disease. Consequently, reductions in the level of research contract support will exert an indirect impact on basic research.

NATIONAL BONE MARROW DONOR PROGRAM

Question. The contract for the National Bone Marrow Registry has recently been transferred to your Institute from the Department of the Navy. What is the status of this program?

Answer. The National Marrow Donor Program has five parts. First, there is a series of more than 50 marrow donor centers recruiting volunteers willing to be listed under code in a national registry with their HLA-types. Second, more than 20 major bone marrow transplant centers around the country with qualifications to do marrow transplants using unrelated marrow donors are linked to the national registry. Third, the Program maintains a repository of living frozen blood cells from each donor-recipient pair transplanted as a resource for future research. Fourth, an evaluative research component studies altruism and the motivation behind marrow donors and studies the outcome of marrow transplantation from unrelated donors. Finally, a coordinating center links all of these together in a fully functional program.

When a qualified transplant center has a patient in need of a marrow transplant but without a suitable related donor, they may access the National Registry of more than 35,000 willing donors. If a thorough evaluation reveals a suitable match, marrow is collected at a site near where the donor lives and transported to the transplant center where it is infused into a patient who has been carefully prepared in advance. More than 120 transplants have been done in this fashion since the first one in December 1987.

Question. How will you fund it in FY 1990?

Answer. Funds are available in the FY 1990 President's Budget to continue this program. Because of the decrease proposed by the President's Budget in research contracts, the Institute will

request approval to reprogram funds to meet the needs of this program.

AIDS

Question. Should we be concerned about the safety of the blood supply?

Answer. The Institute is very much concerned about the safety of the Nation's blood supply. The recognition that human immunodeficiency virus (HIV), the causative agent of AIDS, can be transmitted by blood transfusion has raised important questions regarding transfusion safety. While significant advances have been made in detecting and inactivating HIV in donated blood and plasma, as well as in discouraging potential donors who are at risk for AIDS, there is still a small risk of contracting HIV infection through blood transfusion. In a study being supported by the NHLBI, it was found recently that the risk of becoming infected, after being transfused with blood that was screened for antibody to HIV, is 0.003 percent per unit. The Institute is currently supporting several studies to improve further the safety of the blood supply. These studies are not only focusing on HIV-1, but also on HIV-2 another agent known to cause AIDS and a potential threat to the safety of the blood supply and on HTLV-I a virus known to cause leukemia and a chronic neurological disorder. Other studies deal with hepatitis viruses such as non-A,non-B hepatitis virus.

Question. What is the accuracy of the blood tests for AIDS virus?

Answer. The accuracy of the current generation of assays to detect antibody to HIV-1 is excellent as evidenced by the low risk of acquiring infection from screened blood. The Institute is currently supporting several projects to develop and evaluate new assays to detect HIV-1 and other human retroviruses with even greater accuracy.

HEMOPHILIA

Question. Members of the hemophilia community, both physicians and patients, are concerned about the shortage of Factor VIII. Why is there a shortage, and will it last?

Answer. Estimates of supplies indicate that they are only 30 to 40 percent of what they had been in January 1988. Shortages are expected to persist throughout 1989. The underlying reasons for this shortage are multifactorial. Major reasons for the shortage are abandonment of intermediate purity concentrates in favor of higher purity ones and the abandonment of dry-heating in favor of wet-heating as a means of inactivation of infectious agents by all but one manufacturer. Preliminary clinical data support the effectiveness of these new viral inactivation methods in reducing the risk of transmission of HIV and other viruses, although reductions in yield occur when these processes are employed. High purity monoclonally derived products also result in reduced Factor VIII yields. Thus, more plasma must be used to produce a constant number of Factor VIII units. A third contributing cause of the Factor VIII shortage is the withdrawal of approximately 100 million

units of dry-heated concentrate by the American Red Cross. Apparently, a few donors in each pool were not certain to have met all of the criteria for suitability as specified in FDA regulations. The American Red Cross has been responsible for 20 to 30 percent of the Factor VIII supply.

Question. What measures are taken to alleviate this problem?

Answer. The Medical and Scientific Advisory Council of the National Hemophilia Foundation (NHF) has made several recommendations to improve the rapidly deteriorating situation with respect to the availability of Factor VIII. They intend to work with industry and government to explore ways to increase supply. NHF plans to propose legislative and regulatory initiatives at the Federal level to enhance reimbursement and financing mechanisms. Furthermore, they recommend an expedited review and approval of new processes directed at improving the Factor VIII supply. Lastly, the Factor VIII shortage has prompted close scrutiny of inventory procedures by both the NHF and hemophilia treatment centers and hospitals. A central point of distribution, rather than field inventories, is seen as a more efficient and equitable means for distribution of Factor VIII. Although the NHLBI is not directly responsible for regulating blood, blood components, or plasma derivatives, staff of the NHLBI furnish information and advice upon request.

Question. Tell me about your research program in AIDS.

Answer. The Institute supports AIDS research that will help ensure the safety of the Nation's blood supply and will improved understanding of the effects of the AIDS virus on the heart and lung.

Much of the progress in understanding transfusion-transmitted AIDS has been a result of NHLBI-sponsored investigation. An NHLBI study first demonstrated that HIV could be spread by blood transfusion. Another NHLBI study determined that AIDS was not transmitted by casual contact, but rather through sexual contact or by contact with blood or blood products.

The NHLBI currently is supporting research to determine the frequency of HIV infection in blood donors and to assess the efficacy of blood tests for the virus. Investigators are now concerned that infected blood may test negative for the virus, potentially escape detection, and be transfused. The NHLBI is supporting efforts to develop new, more sensitive tests for HIV viral detection that would eliminate this possibility. One such technique currently under investigation is a test that detects small amounts of viral DNA.

The Institute also is funding studies to develop methods to inactivate viruses in blood and blood products. Treatments that inactivate any HIV in Factor VIII are now available so that this product now can now be given to hemophiliacs without risk of infection. Other blood components such as red cells, platelets, and other plasma proteins cannot withstand heat treatment and the NHLBI is supporting work on methods that can be used on these components.

Future NHLBI research plans include study of other retroviruses like HTVL-I which may pose a threat to the Nation's blood supply.

The major cause of death in persons with AIDS is the result of pulmonary complications. The NHLBI is supporting research on the pulmonary complications associated with AIDS. The impact of early diagnosis of pulmonary infection is being studied, as well as the efficacy of various diagnostic techniques. Future efforts will involve research on the pulmonary and cardiac complications in children who are already infected by the virus at birth.

As many as 50 percent of individuals with AIDS have abnormalities of the heart. NHLBI is supporting research which might lead to identification of possible causes of cardiac dysfunction and hopefully, will lead to an effective treatment of this problem.

The NHLBI is committed to continued research to ensure that the blood supply is safe and that all that is possible is being done to understand and treat effectively AIDS-associated cardiac and pulmonary complications.

CHOLESTEROL

Question. More Americans are having their cholesterol levels checked through public screening. Are there any problems associated with public screening and what steps are being taken to improve it?

Answer. Public screening of cholesterol levels is becoming increasingly popular as a result of growing awareness about the importance of cholesterol and the introduction of machines which allow rapid, nearly painless, and relatively inexpensive measurement of cholesterol from a fingerprick blood specimen. Public screenings involving thousands to tens of thousands of people are occurring with increasing frequency. Public screening has a possibility of detecting large numbers of individuals with high blood cholesterol levels in addition to those detected in physicians' offices. Unfortunately, the reliability of cholesterol measurements and the education and follow-up in public screening programs are often inadequate. Results of current research on screening programs were presented at an Institute workshop on public screening for high blood cholesterol in October 1988. This workshop set standards for equipment, reliable measurement of cholesterol levels, appropriate patient and professional information, staff training, and referral for such programs and proposed the following objectives for public cholesterol screening:

To detect individuals with high levels of blood cholesterol and make appropriate referral to a source of medical care;

To raise public consciousness and knowledge about coronary heart disease and blood cholesterol;

To provide information about eating patterns and other approaches to achieve and maintain appropriate levels of blood cholesterol; and

To reach those who might not otherwise have their blood cholesterol measured as part of routine health care.

Question. We are hearing a great deal about HDL-cholesterol - the so-called "good cholesterol". What is the status of research in this area and what should the American public do regarding HDL-cholesterol?

Answer. Several important avenues of research have established that high density lipoprotein cholesterol (HDL-C), the so-called "good cholesterol", offers a measure of protection from coronary heart disease. A recent analysis of four major U.S. studies showed that the higher the HDL-C level the lower the subsequent risk of coronary heart disease (CHD) and that risk fell by 2 to 3 percent for each 1 mg/dl (2.5 percent) increment in HDL-C. The relationship was even more marked in women and was also seen in older Americans. Clinical trials of lipid altering drugs have suggested that raising HDL may independently contribute to the reduced risk of CHD. Despite these findings there is much to be learned regarding HDL-C. It has proved difficult to find suitable animal models to study the role of HDL. While metabolic studies suggest that HDL may remove cholesterol from arteries, this is not yet clearly established. A clinical trial in which HDL change is the sole or major intervention is proving difficult to design. Pilot studies of some of these issues are being considered by advisory committees to the NHLBI.

Meanwhile it would seem prudent that individuals with low HDL, who are at greater risk for coronary disease, adopt hygienic measures such as weight control, moderate exercise, and cessation of cigarette smoking. These measures may raise HDL levels and are, of course, beneficial in many other respects.

Question. To what extent should elderly Americans be a focus for the reduction of cholesterol levels?

Answer. While the general importance of cholesterol-lowering in the prevention of coronary heart disease (CHD) is now widely accepted, its application to the older patient is not yet well defined. The association between blood cholesterol levels and CHD morbidity and mortality weakens with age. However, because age itself is a major risk factor for CHD, treatment of hyperchloesterolemia in the elderly may bring about a greater reduction in absolute risk than is obtained in younger persons. More research is needed that directly addresses the benefits of treatment of hypercholesterolemia in the elderly. To this end, the NHLBI is initiating a pilot study of a trial of one of the new powerful cholesterol-lowering HMG CoA reductase inhibitor class of drugs. This study will simultaneously address several issues by seeking to determine if cholesterol lowering will benefit: older as well as younger Americans; women as well as men; and individuals whose cholesterol is only moderately elevated.

In addition, given the excellent cholesterol-lowering ability of this new class of drugs, the study will assess whether CHD can be reduced to a much greater extent than with less powerful cholesterol-lowering drugs.

Question. In the newspapers we see many articles about cholesterol. There seems to be a bad cholesterol and a good

cholesterol. In addition, there are other components called apolipoproteins. Can you explain to me the meaning of these terms?

Answer. The cholesterol in the blood is carried in several fractions called lipoproteins. About 70 percent is carried in a fraction called low density lipoprotein (LDL), the so-called bad cholesterol. The higher the LDL level, the greater the chances of cholesterol forming fatty deposits in arteries. This can lead to coronary heart disease and heart attacks.

Normally about 25 percent of the plasma cholesterol is in another fraction called high density lipoprotein (HDL). The higher the HDL level, the less the risk of coronary heart disease, that is, HDL seems to protect against coronary heart disease.

It is well established from clinical trials that reducing LDL levels reduces the risk of coronary heart disease and there is suggestive information that raising HDL may protect against heart disease.

The apolipoproteins, also sometimes known as apoproteins, are the protein component of the lipoprotein particles. By being attached to apolipoproteins, fatty materials such as cholesterol are dissolved in the blood. Many apolipoproteins have been identified to date. The apolipoproteins have various important functions. Abnormalities involving certain apolipoproteins underlie certain diseases, some common, some rare.

The higher the levels of apoprotein B, the major apoprotein of LDL, the greater the risk of coronary heart disease. The higher the levels of apoproteins AI and AII, the major apoproteins of HDL, the less the risk of coronary heart disease. However its not clear whether knowing the levels of these apoproteins materially improves the assessment of the risk of coronary heart disease over knowing the levels of LDL and HDL.

NATIONAL CHOLESTEROL EDUCATION PROGRAM

Question. What is the status of your cholesterol education program?

Answer. The National Cholesterol Education Program (NCEP), which has been in existence for only three years, has succeeded in forging a partnership among a wide range of private and public sector organizations and has catalyzed the development of a nationwide campaign directed to health professionals and the public. The primary focus has been on promoting the detection and treatment of adults who are at high risk for coronary heart disease because of high blood cholesterol levels. The NCEP has developed and distributed to over 150,000 physicians new guidelines for the treatment of high blood cholesterol in adults, together with educational materials for patients that explain the basics, especially how to make dietary changes to lower high cholesterol levels. The program has developed recommendations for improving the accuracy of cholesterol measurements in clinical laboratories and has distributed guidelines for public screening programs. An ongoing mass media campaign has been urging the public to know their cholesterol number. The first National Cholesterol

Conference, held in November 1988, drew over 1500 professionals eager to share information about cholesterol control. At the same time that the NCEP has pursued this "high risk" approach, it has also begun to build the foundation for additional strategies. A panel is developing recommendations for cholesterol-lowering actions by the general population, especially changes in eating patterns, to reduce the average cholesterol level in the United States, and another panel has just been established to develop recommendations concerning cholesterol levels in childhood.

Question. Do you believe it has an impact on the health of the American people?

Answer. In our view, the NCEP is having an impact on the health of the American people. A variety of indicators demonstrate that the program is making gratifying progress. Data from the FDA show that from 1983 to 1988 the percent of the public who were convinced that lowering high blood cholesterol would have a large effect in preventing coronary heart disease (CHD) rose from 64 percent to 77 percent; the percent who reported having their cholesterol checked rose from 35 percent to 59 percent and Gallup poll data from 1989 show this figure is up to 66 percent; the percent who knew their cholesterol levels rose from 3 percent to 17 percent; and the percent who cited fatty foods as a cause of heart disease rose from 29 percent to 55 percent. From 1982 to 1988, patient visits to physicians for hypercholesterolemia went up over 800 percent. We think that the education efforts of the NCEP are raising awareness and promoting better health behaviors regarding cholesterol, and we will be looking for the effects of these changes on blood cholesterol levels and on CHD rates. Based on the progress indicators and the evidence from clinical trials, we believe that the NCEP is helping to reduce the risk of heart attacks and making a significant contribution to the health of the American people.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

NATIONAL BONE MARROW DONOR PROGRAM

Question. Dr. Lenfant, last year this Committee provided up to $1.5 million to facilitate the transfer of a National Bone Marrow Registry from the Department of the Navy to the NIH. I understand the registry is now located in the National Institute on Heart, Lung, and Blood. What is the status of the Bone Marrow Registry?

Answer. The National Marrow Donor Program has five parts. First, there is a series of more than 50 marrow donor centers recruiting volunteers willing to be listed under code in a national registry with their HLA-types. Second, more than 20 major bone marrow transplant centers around the country with qualifications to do marrow transplants using unrelated marrow donors are linked to the national registry. Third, the program maintains a repository of living frozen blood cells from each donor-recipient pair transplanted as a resource for future research. Fourth, an evaluative research component studies altruism and the motivation behind marrow donors and studies the outcome of marrow transplantation from unrelated donors. Finally, a coordinating center links all of these together in a fully functional program.

When a qualified transplant center has a patient in need of a marrow transplant but without a suitable related donor, they may access the National Registry of more than 35,000 willing donors. If a thorough evaluation reveals a suitable match, marrow is collected at a site near where the donor lives and transported to the transplant center where it is infused into a patient who has been carefully prepared in advance for the marrow. More than 120 transplants have been done in this fashion since the first one in December 1987.

Question. Are there sufficient funds included in the President's FY 1990 request to maintain a fully functional registry?

Answer. Funds are available in the FY 1990 President's Budget to continue this program. Because of the decrease proposed by the President's Budget in research contracts, the Institute will request approval to reprogram funds to meet the needs of this program.

NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF HARALD LÖE, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next we will go to the National Institute of Dental Research. Dr. Löe?

Dr. LÖE. Thank you, Mr. Chairman. Last year when I testified before this committee, I alluded to a major survey that we had just completed regarding the prevalence and severity of dental diseases in U.S. schoolchildren. Approximately, 40,000 children were surveyed, which is highly representative of a population of about 40 million children. This year I am able to report to you that the data show that approximately 50 percent of America's schoolchildren have had no tooth decay whatsoever—never had a filling, never had a cavity.

This is a spectacular achievement and is probably unsurpassed in the world.

Senator HARKIN. Fifty percent of school-age children. That is from age 18 on down?

Dr. LÖE. Ages 5 to 17. Half these children never had any cavities, and those who did have some tooth decay had 30 percent less than their age-matched children in 1980.

Senator HARKIN. What do you attribute that to? Fluoride?

Dr. LÖE. There are several factors involved here. First of all, I think the diet is much better than it used to be. In the past, every child had tooth decay; caries was, and is, the most common disease in the United States. Costs associated with caries remain the third most costly to the public. We spend approximately $27.1 billion per year for the national dental bill, but the decrease in tooth decay in children has saved about $3 billion per year, which is a substantial amount of money.

Senator HARKIN. Has fluoridation helped?

Dr. LÖE. Fluoridation has been very important, not only in water, but also through topical application and as an additive in toothpaste and other vehicles.

Senator HARKIN. I remember when I was in high school, or college, when they started putting fluoride in water, and a lot of people said it was a big Communist plot. Do you remember that?

Dr. LÖE. Yes; I remember that. It is probably the most beneficial Communist plot we have had.

Despite our successes, 50 percent of our children still have tooth decay. So, our job is not over yet. Furthermore, it appears that 20 percent of the children have 80 percent of the disease. We have a subgroup of children that are more susceptible to the disease than others. Our work continues toward our aim to eliminate tooth decay in America's children.

ORAL HEALTH AND THE ELDERLY

We are also seriously concerned about the oral health needs of adults and older Americans. Our adult survey has shown that approximately 40 percent of Americans 65 and over have lost all their teeth. Those who still have teeth continue to experience tooth decay and periodontal disease, and to suffer from these diseases more than any other age group.

We are committed to doing whatever we can to help today's older Americans. And at the same time, it is essential that we focus on younger adults to ensure that the improvements that we are now seeing in this segment of our population are maintained through their retirement years. In accordance with this concept, we are mounting a major initiative that we call "The Research and Action Program for Improving the Oral Health of Adults and Older Americans." A report on our progress in this initiative was forwarded to this committee in December 1988.

The goals of this program are, essentially, to eliminate toothlessness in America in the course of the next 20 years. In the past, most of the activity within the NIDR has been prevention and basic research—prevention as it relates to children, first of all. These investments in basic research and in prevention have paid off, as I have just told you. However, we have had very little prior investment in the oral health of adults and the elderly. It is clear that we need to investigate the changes occurring in the mouth and the jaws in the course of normal maturity and aging.

As we age, we experience changes in the composition of bacterial flora, declines in immune reactions, bone and soft tissue changes, and modifications in wound healing and regenerative capabilities. We need to compare those changes with what happens as a result of oral and systemic diseases, which also have consequences for oral health and dental treatments.

The action side of the Research and Action Program includes health promotion efforts targeted directly to the public and to health care providers. So far, this has been an initiative on the part of NIDR, but we are seeking the cooperation of other Government agencies, organized dentistry, private industry, and consumer groups in this effort. A major theme that is emerging from this planning activity is the increasing need for clinical research and for clinical research training. We have been encouraging movement in this direction through career development programs, such as our Dentist-Scientist Award. We are extremely grateful for the consistent support of this program by this committee.

We also endorse the recommendation of an NIDR advisory panel to initiate clinical core research centers in dental schools. Such centers would provide the state-of-the-art resources and equipment necessary for conducting clinical studies and clinical trials.

PREPARED STATEMENT

Mr. Chairman, our budget for 1990, without AIDS funding, is $131,527,000, which is essentially a 3.2-percent increase over the 1989 comparable amount. I would be delighted to respond to your questions.

[The statement follows:]

STATEMENT OF HARALD LÖE

Mr. Chairman, the National Institute of Dental Research celebrated its 40th anniversary last year. As we reviewed the past and addressed the future, it was clear that 1948 marked a turning point in dental science. The act of Congress establishing the NIDR moved dental research to center stage, mobilizing forces that have led to revolutionary advances in oral health in America.

We have seen those advances in terms of children's health. The results of our latest national survey showed that 50 percent of the youngsters between 5 and 17 years are caries free. Those who have caries experienced significantly fewer and smaller cavities than children examined as recently as 1980.

The good news does not mean that our job is over. Fifty percent of children still experience tooth decay. We will continue to work to reduce the prevalence of caries in children, particularly in improving methods of identifying and helping those who are most susceptible to tooth decay.

However, we are seriously concerned about the oral health needs of adults and older Americans. Over 40 percent of Americans 65 and over are toothless. Those who still have teeth continue to experience decay on the crowns and roots of teeth and suffer more severe and extensive periodontal diseases than any other age group. Further, our studies were based on people healthy enough to be seen at senior citizen centers; the oral health of homebound or nursing home residents may be worse.

The younger, employed adults examined in our survey showed significant gains in oral health compared to a generation ago. Nevertheless, they averaged 23 cavities or fillings, and the majority had some form of periodontal disease. Again, the oral health of groups not included in the study, such as farm workers and the permanently unemployed, may be worse.

After publication of our findings, we met with experts in the dental community to discuss the implications for research. We universally agreed that all that could be done, should be done for the oldest aged groups. Further, we concurred that we should increase our emphasis on the oral health of young and middle-aged adults to ensure that the recent improvements we have seen will be maintained through the retirement years. The result of these deliberations is a major initiative called "The Research and Action Program for Improving the Oral Health of Adults and Older Americans." Progress in this program is summarized in a report requested by the Subcommittee and submitted in December, 1988.

The goals of this program are to eliminate tooth loss in future generations and prevent further deterioration of the oral health status of individuals with compromised dentitions. This calls for a comprehensive program for generating new knowledge and translating it into clinical practice and appropriate self care.

NIDR has responsibility for the "research" side of the Research and Action Program. Since much of what we know about oral diseases and prevention is based on studies of children, it will be important to investigate the changes occurring in the oral cavity in the

course of normal maturity and aging--changes in the composition of oral bacteria, for example, as well as declines in immune function and wound healing--and compare those changes with what happens as a result of oral and systemic diseases. Diabetes, heart valve disease, and rheumatoid arthritis are just a few examples of prevalent conditions in adults which have consequences for oral health and dental treatments. In addition, oral health depends on lifestyle, diet, the use of medications, income and other demographic variables. To determine which of the many factors involved are predictive of risk, researchers will be looking at existing survey data and conducting long-term prospective studies of adults. The oral applications of new diagnostic methods such as genetic and antibody probes, nuclear medicine, magnetic resonance imagery, and subtraction radiography must also be assessed. These and other technologies and treatment interventions will ultimately be the subject of clinical studies and clinical trials. Field demonstration research will be undertaken to evaluate which preventive measures, or combinations of preventive and restorative measures, work best in adults.

The "action" side of the Research and Action Program includes efforts targeted directly to the public and to health care providers. We are seeking the cooperation of organized dentistry, other government agencies, private industry, consumer groups, and community leaders in this effort. Initial contacts with the Centers for Disease Control, the Health Resources and Services Administration, the Chief Dental Officer of PHS, the American Dental Association, the American Association of Dental Schools, the American Dental Hygienists' Association and other groups have been overwhelmingly positive, with commitments of personnel and resources.

The Research and Action Program is not the only aging-related initiative in place at NIDR. Collaborations with the National Institute on Aging and the Department of Veterans Affairs are continuing. Last year, in response to a joint Request for Applications, the NIDR awarded its first grant for a research center on oral health in aging to the University of Florida College of Dentistry in Gainesville. Among the projects supported are epidemiological studies, research on periodontal diseases, and investigations of sensory functions such as taste and smell, in older people.

These center projects will further the goals of our Research and Action Program. In turn, the goals will be incorporated into a new NIDR Long-Range Research Plan for the Nineties. A major theme emerging from this new planning activity is the emphasis on clinical research and research training.

NIDR has long recognized the importance of clinical research. In its 1985 report to Congress on the Use of Centers and Other Large Grant Mechanisms, the Institute endorsed the recommendation of an advisory panel to initiate clinical core research centers. Such centers provide the resources and equipment needed to facilitate the conduct of research by basic and clinical scientists focusing on a common area. In addition, the Institute has worked to augment the pool of clinical research investigators through research training and career development programs, such as the Dentist-Scientist Award. These programs are vital as a means of generating clinical scholars, not only to speed the movement of research from laboratory to dental office, but also to supply the dental school faculty to train tomorrow's dentists.

The future of dentistry is more exciting than ever; it is a future in which the education of dentists will prepare them to diagnose, treat, and ultimately prevent the entire range of oral health problems, including oral cancers, chronic orofacial pain, joint problems, salivary gland dysfunctions, and disorders of taste, smell and swallowing.

In terms of children's health, the role of dentists will not be limited to preventing tooth decay, but will extend to other risks to the oral health of young people, for example, the risk of oral cancer from smokeless tobacco use. Toward that end, the NIDR is supporting a study of Major League baseball players to analyze the effects of smokeless tobacco on the oral tissues and to determine the extent to which these effects are reversible.

Dentists of the future will be more informed and better able to advise women of childbearing age. Historically, dental researchers have been prominent in identifying the severe craniofacial defects and other serious problems that can result from maternal alcohol and substance abuse, the use of prescription medications, such as the popular drugs for acne, and now found in association with infection with the human immunodeficiency virus (HIV). In other research, investigators continue to study the genetic-environmental interactions that can result in cleft lip and cleft palate. They are devising better methods of repairing these common birth defects and restoring normal breathing and speech patterns.

This expansion of dental research into developmental biology and genetics, into oral soft tissues diseases, cancer studies, and AIDS, underscores how far dental research has progressed in four decades. The decades of the fifties and sixties were of major importance in establishing that both caries and periodontal diseases were infectious diseases associated with bacteria in dental plaque. These discoveries set the stage for the recruitment to dental research of microbiologists, immunologists, biochemists, geneticists and other biomedical and behavioral scientists.

Their explorations of the oral cavity have evolved into the field of oral ecology: the study of the interactions of the oral tissues with the microorganisms, nutrients, dental materials, and other substances found in the mouth. Out of these studies have come discoveries about how bacteria colonize specific sites, how the soft tissue lining the mouth acts as a barrier to shield the body from foreign invaders, how saliva fights infections, and how the oral tissues themselves are protected, nourished, and repaired. Each new finding has opened up new approaches to treatment and prevention--from genetic modifications rendering harmful bacteria harmless, to the use of growth factors to stimulate new bone formation in advanced periodontal disease.

Oral ecology research is providing insight into the study of the oral complications of HIV infection. The weakened immunity resulting from HIV infection upsets the balance of the oral ecosystem, inviting overgrowth of destructive bacteria and fungal organisms normally kept in check by a variety of local and systemic mechanisms. Clinically, this can result in oral candidiasis, herpes and papilloma virus infections, and severe periodontal disease in HIV infected individuals, as well as Kaposi's sarcoma and hairy leukoplakia. Often these oral signs and symptoms may be the first

indication that a patient is infected with HIV, a fact that underscores the importance of the dentist in the present epidemic. Not only can the dentist offer counsel and refer the patient for testing and follow-up care, but the treatment of the oral lesions themselves may prevent the spread of infections to lungs or digestive organs where the infection may be fatal.

Interestingly, the oral environment is not attractive to HIV itself. Investigators now have repeated earlier studies that showed that normal human saliva, as well as saliva from HIV-infected patients, contains a factor that inhibits the infectivity of the virus, thus adding weight to other evidence suggesting that there is little risk of transmission of HIV through saliva.

The NIDR commitment to AIDS research includes epidemiological studies of the natural history of oral complications, analysis of HIV proteins, production of anti-HIV monoclonal antibodies, immune cell studies, and, recently, the development of the transgenic mouse model of AIDS. The transgenic mice were produced by an NIDR intramural scientist who implanted HIV genetic material--supplied by colleagues in the National Institute of Allergy and Infectious Diseases--into fertilized mouse cells. Later, offspring of one transgenic mother were produced which showed AIDS-like symptoms, dying at the age of three or four weeks. Prior to the development of the model, only human beings and chimpanzees could be infected with HIV and only humans became sick.

Salivary studies also are continuing. In addition to the research on an anti-HIV factor, investigators are studying the saliva of relatively healthy HIV-infected individuals. The scientists have documented changes in the composition of saliva which suggest that oral defense mechanisms are compromised early in the course of infection. If these results are confirmed and shown to be specific for HIV infection, they could lead to the design of a diagnostic test for HIV infection. In addition, they underscore the importance of providing oral prophylaxis as part of the routine management of HIV infected persons. Such care should lower the risk for oral complications as well as the potential of infectious agents gaining access to vital organs or the bloodstream via the oral route.

We are excited about the contributions that dental research is making toward the conquest of AIDS. It is a major example of the research advances made possible by 40 years of federally supported dental research and augurs well for the future of the science and of the profession of dentistry.

Mr. Chairman, the FY 1990 budget request for the National Institute of Dental Research is $131,527,000. I will be happy to answer any questions.

ORAL DISEASES

Senator HARKIN. Is it under your jurisdiction—where they, where you might have research going into certain things like mouth diseases, like canker sores, things like that? Is that under——

Dr. LÖE. Yes, sir; that is our area.

Senator HARKIN. You did not mention anything about it.

Dr. LÖE. We study all the problems that can affect the mouth, including canker sores and cold sores. We have had a major development in the last few years in research on cold sores because these lesions tend to be more stubborn and also because similar lesions occur in the genitals.

Senator HARKIN. I am amazed when I talk to people, how many people are affected by canker sores, among the general populace.

Dr. LÖE. Next year, I will be able to give you the exact figures for the prevalence of canker sores and cold sores in children and in adults, but exact data are not available at this time.

Senator HARKIN. Do you have any data at all?

Dr. LÖE. I would estimate that half the population experiences canker sores and three-fourths have been infected with the agent that causes cold sores, the herpes simplex virus. About 50 percent of those infected have one or more recurrences of herpes in the course of their lives.

Some of them, 20 or 30 percent, have greater reoccurrences of the herpes simplex virus and the associated cold sores.

Senator HARKIN. Do you know what causes it?

Dr. LÖE. Yes; herpes simplex is a viral disease—an infection occurring very early in life. The latent virus is reactivated by several factors, such as sunlight or stress. Cold sores appear somewhat regularly due to these factors.

We have been working on both the treatment of cold sores and a vaccine to prevent them. I think we have made some headway in both areas.

Senator HARKIN. I would like to know.

Dr. LÖE. We would be delighted to send you more information.

Senator HARKIN. The doctors I have talked to say this is something more widespread than people even imagine.

OVERLAP WITH DEAFNESS INSTITUTE

To what extent are your research project grants in the areas doing with taste, smell, speech, language, overlapping those in the Deafness Institute.

Dr. LÖE. We appropriately maintain responsibility for speech and language research related to orofacial defects such as cleft lip and palate. Similarly, taste and smell research directly related to oral diseases and conditions remain the responsibility of NIDR.

Although there is a certain overlap, it is not significant. All Institutes overlap to some extent, especially in the basic sciences such as microbiology and immunology.

Senator HARKIN. Should they be transferred?

Dr. LÖE. I do not think so, since our efforts are concentrated on orofacial and oral diseases and conditions. I believe it would be appropriate to establish a formal coordinating mechanism, however.

DENTAL SEALANTS

Senator HARKIN. What is a dental sealant?

Dr. LÖE. A dental sealant is a compound that is painted on the chewing surfaces of the back teeth of children. It prevents bacteria from settling into these rough surfaces, where toothbrush and fluoride cannot reach. This is a way of sealing out tooth decay, and it is a very effective one.

Senator HARKIN. Do all dentists do that now with children?

Dr. LÖE. They should be doing it, but we have found that less than 10 percent of children benefit from this technology, which is really too bad, because it is a very effective one.

Senator HARKIN. How long does the sealant last?

Dr. LÖE. The sealant will last for approximately 6 or 7 years, but can be repainted at the cost of some $10 per tooth. The use of sealants should be encouraged, because children clearly benefit from it. Two-thirds of the tooth decay is appearing in the chewing surfaces. By applying sealants, we could, practically speaking, eliminate tooth decay in these children.

Senator HARKIN. That is about all I have. Do you have anything?

DECLINE IN DENTISTRY

Senator REID. Thank you, Mr. Chairman.

From what you have described, most of the procedures now are against the best interest of the dentist—if people do not come back. Is that right?

Dr. LÖE. I do not think so. It has always been the goal of the dental profession to eliminate dental disease.

Senator REID. I read an article in Business Week awhile ago that indicated that that is one of the worst professions to go into there is now, dental work, because their business is not good. People's teeth are in good shape.

Dr. LÖE. I do not agree. Dentistry is still a very vibrant profession, and most dentists are making a good living. However, enrollment in dental schools has declined by about 30 percent over the last 10 years. This adjustment should be sufficient to maintain a reasonable balance between supply and demand.

WELFARE PROGRAM COVERAGE FOR DENTAL WORK

Senator REID. My question—when I first became Lieutenant Governor, a woman came to see me that worked for the State Welfare. And she came, not wanting anyone to know that she came to visit with me. But her concern was that most welfare programs do not cover teeth in children.

Then she went on to state that it is one of the real problems we have in our society, because someone has—they may have no cavities in their teeth, but if they are crooked, it can cause speech impediments. It can cause people to talk with their mouth covered. It just causes all kinds of personality problems.

I have not read your statement, but I have tried to listen to you during these proceedings. Is there anything going on with the work on orthodontics, braces for children? Do you, in fact, know if most

State welfare programs cover orthodontics, and dental work, generally, for teeth of children?

Dr. LÖE. Senator Reid, I am sure you realize that the National Institute of Dental Research has really nothing to do with the regulations and the funding of welfare programs.

Senator REID. But if you have all these statistics, I would think you would have that information.

Dr. LÖE. I realize that. I appreciate your sensitivity to the program, because there is a real problem here.

There is no question that there are subgroups of the population that have more disease than others, and that do not get treatment for these diseases, including orthodontic treatment. To what extent this can be rectified by an increase in the reimbursement for these treatments, I have no idea. But I would expect the more we can fund these programs, the better the teeth of the children will be. We would be much in favor of endorsing that kind of a development.

Let me give you one example of the data I have on this particular subgroup of the population. Water fluoridation works for all social groups. It is in the tap water, and everyone, rich and poor, has access to this type of water. There is no question that we have reduced tooth decay in disadvantaged children.

However, when they do get tooth decay, they do not get treatment. So the consequences of getting a few cavities would have a very different effect on these children than on those who can enjoy dental care, and the payment for it.

There is no question that there are groups that are more at risk, and they are disadvantaged, as compared with others. I certainly agree with you.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much.

There will be some additional questions which will be submitted for your response in the record.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

UNIVERSITY OF IOWA LONGITUDINAL STUDY

Question. People I have talked to at the Caries Research Center at the University of Iowa have told me of the Iowa Longitudinal Study which has been under way for 5 years. This is a study to track, over time, dental health among the aging population. While dental health in the American population is very good, over 40 percent of the men and women 65 years old and older are missing all their teeth. Those who still have teeth continue to experience tooth decay and suffer more severe and extensive gum diseases than do younger adults.

What have we learned from the Iowa Longitudinal Study, and what do we know generally about steps that need to be taken to improve oral and dental health among our older population?

Answer. From the Iowa and other studies, including our own epidemiologic research, it is clear that oral diseases continue to be a major problem among the elderly. This is partly because older persons did not have the benefit of modern methods of decay prevention as children and adolescents; however, it has also been established that many of the elderly continue to develop active disease, both caries and periodontal disease.

In responding to this problem, the NIDR has begun a major initiative called the "Research and Action Program for Improving the Oral Health of Adults and Older Americans." This initiative is designed to spur the basic and clinical research necessary to drive nationwide public and private sector actions to improve the oral health of all Americans. The explicit goal of the program is to eliminate tooth loss in the U.S. population and prevent further deterioration of the oral health status of individuals who have a compromised dentition. The NIDR role will be to expand the knowledge base and accelerate the transfer of laboratory findings to the public and to the profession. The Institute is emphasizing research on normal changes in the oral tissues and the body's defense mechanisms in aging, and how these changes are affected by disease, diet, medications, environment, and lifestyle. Epidemiologic and behavioral science research will be essential to document the prevalence of oral diseases in special populations (e.g., the frail; the handicapped), identify risk factors, advance prevention research, and monitor science transfer.

OVERLAP WITH PROGRAMS OF THE DEAFNESS INSTITUTE

Question. The new Deafness Institute has responsibility now for diseases and disorders associated with taste, smell, speech, and language. These fields have previously, at least to some extent, been the jurisdiction of the Dental Institute. To what extent are your research project grants in these areas overlapping activities to be conducted by the new Deafness Institute?

Answer. No significant overlap is anticipated, since continuation of the same divisions of responsibilities negotiated earlier with the NINCDS are planned. NIDR appropriately maintains responsibility for speech and language research related to orofacial defects such as cleft lip and palate. All other speech research remains the responsibility of the new Deafness Institute. Similarly, taste and

smell research directly related to oral conditions and diseases remain the responsibility of NIDR; other taste and olfactory research will be supported by the NIDCD.

Recently, NIDR and NIDCD issued a joint program announcement calling for research grants on oral-motor function, which clearly indicates the mutual, but distinct, interests of NIDR and NIDCD in this topic. Staff of both Institutes will continue close coordination of these research activities to ensure that complementary, non-overlapping efforts are made to advance progress in all these areas.

DENTAL SEALANTS

Question. I understand that the dental community now recommends that all children should be provided with dental sealants. A very small percentage of the population actually have had dental sealants applied to their teeth. Could you describe for the Committee the benefits of dental sealants, and what is being done to encourage the American public to have dental sealants?

Answer. The widespread availability of fluorides in drinking water, dentifrices, mouthrinses, tablet and drop supplements, and from professional treatments has drastically reduced the amount of decay on the smooth surfaces of children's teeth. The majority of decay that remains is on the chewing surfaces of back teeth, which are the least benefitted by fluoride. By sealing over the decay-prone pits and fissures on the chewing surfaces, sealants virtually eliminate the risk of decay in these areas.

Unfortunately, sealant usage has not increased rapidly in the past decade. Only 8 percent of school-aged children have received sealants. A number of strategies are being pursued to increase usage of this technique. For example, NIDR continues to promote sealants through the distribution of pamphlets and posters and to work with mass media in providing information to science writers and editors. We have worked with the Ohio Department of Health, the American Dental Hygienists Association, and the Johnson and Johnson Dental Products Company to produce public service announcements and an award-winning video on sealants. The video is being distributed to all state health departments and other outlets.

The NIDR recently presented data on national sealant utilization from its 1986-87 child oral health survey at the meeting of the American Association for Dental Research. There was considerable coverage in newspapers and on television around the country highlighting the current low usage levels. NIDR and CDC are co-leads for development of the National Oral Health Objectives for the Year 2000. A draft objective calls for at least half the children 8 through 14 years of age to have their molar teeth sealed by the year 2000.

CENTERS PROGRAM

Question. The Institute established two new centers last year, one that focuses on the dental and periodontal problems of the elderly, and one that focuses on materials for dental implants, for a total now of 18 research centers funded by the Dental Institute. In

a report prepared by the Dental Institute several years ago, it was recommended that core centers be established. These centers would combine basic and applied research along with clinical trials and services. These centers have never been established. Is there still a need for the establishment of core dental centers?

Answer. It is my professional opinion that the need for a core centers program continues, particularly if we are to expedite the translation of basic scientific knowledge into new and better methods for improving the oral health of the Nation.

STATUS OF DENTAL HEALTH VERSUS DEMAND FOR DENTAL PRACTITIONERS

Question. Each year for the past decade, the Committee has been impressed by your reports on the rapid improvement in the Nation's general dental health. What impact is this trend having on the dental practitioner community? Are fewer people entering into dentistry as a profession?

Answer. According to the latest figures from the American Association of Dental Schools, there has been a 25-percent decline in total enrollment in dental schools since 1980 and a 33-percent drop in first-year enrollment since 1978. It is expected that there will be another 2- to 4-percent decline in first-year enrollments for the 1989-1990 entering class.

Question. Are costs for overall national dental care decreasing as the Nation's dental health improves? If not, please explain why.

Answer. Dental expenditures have already begun to feel the impact of improvements in the Nation's oral health. During the 9 years from 1978 through 1986, real growth with inflation factored out has been less than 1 percent annually. This almost total lack of growth in real dental expenditures is remarkable. Most economic factors were moving in a direction to increase demand and expenditure during this period: the total U.S. population was growing, albeit slowly; the supply of dentists was increasing; the percent of the population covered by dental insurance was expanding rapidly; and national income expanded during most of these years.

Question. If the trend toward improvement in dental health continues, what impacts will that trend have on NIDR programs?

Answer. The decline in dental caries in children and the improvements in the oral health of young and middle-aged adults are major success stories of dental research. They indicate to us that we can devote more time and energy to a broader range of oral health problems and focus on those segments of the population that are not enjoying optimal oral health. These groups include large numbers of older Americans and individuals of any age who are at high risk for oral health problems. Their needs form the basis for a major initiative of NIDR, the Research and Action Program for Improving the Oral Health of Adults and Older Americans.

The goals of the program are to eliminate toothlessness in future generations and prevent further deterioration in the oral health of individuals with already compromised dentitions. The

program calls for expanded research, including basic studies of the normal growth, development, and aging of the oral tissues, clinical research on oral cancers, viral infections, and other serious diseases affecting oral hard and soft tissues, and major efforts to develop better methods of diagnosis, treatment, and prevention suited to high-risk populations and older Americans.

Other important NIDR program areas are unaffected by dental disease trends. These include the oral complications of HIV infection, the prevention of orofacial birth defects, treatments for acute and chronic pain, studies of genetic and degenerative diseases of bones and teeth, salivary gland dysfunction, and basic research in microbiology, genetics, and immunology.

Question. What are the top priorities in NIDR research programs today in your view?

Answer. The NIDR Research and Action Program for Improving the Oral Health of Adults and Older Americans is one of our top priorities. Implementing this program will allow expanded research on all the oral health problems that affect mature and older adults; it will permit exploring the interrelations between oral and systemic diseases and their treatments (e.g., diabetes, cancer, arthritis); and it will encourage development of improved diagnostic, treatment, and prevention methods especially applicable to individuals at high risk for oral health problems.

The "action" side of the program is designed to foster widespread cooperative and collaborative arrangements with other public and private agencies and individuals to hasten application and adoption of the results of research by the profession and by the public.

A second major priority is the development of clinical core research centers to permit dental schools and other academic institutions to mount basic and clinical research activities by providing them with state-of-the-art equipment and resources.

A third top priority is research training and manpower development. The future of research depends on the availability of research-oriented clinicians (e.g., D.D.S.-Ph.D. degree holders such as graduates of the NIDR Dentist-Scientist Award Program) as well as Ph.D. scientists trained in basic biomedical or behavioral science fields. These needs are especially important in light of the expansion of the scope or oral health research to include all the diseases and disorders affecting the mouth and face.

ADULT AND ELDERLY DENTAL CARE

Question. As the adult and elderly population of the Nation increases, more attention is being given by NIDR to late-onset periodontal disease and oral health in those populations. How has the adult/elderly oral health program under NIDR progressed over the past year?

Answer. Substantial progress has been made in laying the foundation for an adult oral health promotion program. NIDR has met with a number of organizations, Federal and private, to share the program

concept, goals, and proposed implementation. Because so much emphasis has been accorded to children's oral health issues in the past, some educational work is necessary with the public and health professions regarding the extent of adult oral health problems, modifiable risk factors, and available preventive techniques.

The Centers for Disease Control entered into a partnership with NIDR a year ago in developing a "Research and Action Program for Improving the Oral Health of Adults and the Elderly" by assigning a full-time senior staff person to NIDR. Over the past several months, organizations such as the American Dental Association, American Dental Hygienists Association, American Association for Dental Research, National Dental Association, Indian Health Service, Department of Veterans Affairs, Bureau of Maternal and Child Health and Resources Development, and National Center for Health Services Research and Health Care Technology have been briefed on the plans and have been supportive. In recent months, the rationale for an adult oral health promotion program has been presented at several national meetings and has been well received.

Plans are to establish a Federal steering committee for the activity early in FY 1990, and follow up with the establishment of an external steering group and a consortium of participating organizations. The program--if fully developed--would be tripartite: "Health Promotion and Disease Prevention Research Targeted to Adults"; "Health Promotion and Disease Prevention Activities" carried out at national, State, and local levels through participating organizations; and "Evaluation", including overall program progress and demonstrations of community-based adult oral health promotion activities.

Question. Is dental health in the adult/elderly cohort improving as a result of improved dental practices in society at large?

Answer. The existing data are inadequate to draw firm conclusions about trends in the levels of oral diseases in adults and the elderly. Loss of teeth, especially total endentulism, has definitely decreased in adults below the age of 65. There is some evidence that dental caries in adults may have decreased slightly, at least in persons up to age 35 or 40, though the levels of caries and periodontal diseases are still very high.

Question. What has been the impact of fluoridation of public water supplies over the past 40 or more years?

Answer. We know from earlier studies in naturally fluoridated areas that the dental health benefits gained in childhood carry over into adult life if residence in fluoridated areas continues. Also, we have learned that topical exposure to the continuous presence of small concentrations of fluoride in the oral fluids provides benefits through remineralization of incipient carious lesions. Some studies have also demonstrated that fluoridated water provides significant protection against the occurrence of caries in exposed root surfaces in adults.

The demonstrated effectiveness of various topical fluoride procedures in adults tends to reinforce the importance of a continuous fluoride presence in the oral environment, which is best provided for by community water fluoridation. Although we do not yet have any applicable large-scale epidemiological studies completed, it seems highly probable that these known positive factors are all at work in maintaining better adult dental health in fluoridated areas.

Question. Have any studies of adult/elderly dental health been conducted?

Answer. The most comprehensive study of the oral health of U.S. adults and the elderly was carried out in 1985-1986 by the NIDR. The results of this survey showed that over 40 percent of Americans 65 and over are toothless. Those who still have teeth continue to experience decay on the crowns and roots of teeth and suffer more severe and extensive periodontal diseases than any other age group. Further, our studies were based on people healthy enough to be seen at senior citizen centers; the oral health of homebound or nursing home residents may be worse.

The younger, employed adults examined in our survey showed significant gains in oral health compared to a generation ago. Nevertheless, they averaged 23 cavities or fillings, and the majority had some form of periodontal disease. Again, the oral health of groups not included in the study, such as farm workers and the permanently unemployed, may be worse.

Question. What is your assessment of public awareness efforts?

Answer. Public awareness efforts about oral health directed to adults, particularly the elderly, have been good but they are not as comprehensive as they could be. The NIDR has developed several educational leaflets about oral health that are directed to adults. In addition, in collaboration with the National Institute on Aging (NIA), the NIDR recently revised NIA's "Age Page" on oral health. Further, the American Dental Association has produced educational materials for adults and has recently targeted efforts directed to the elderly. Industry advertises to adults regarding oral health, with much of the major advertising concentrating on denture cleaners or adhesives. Overall, an organized, coordinated campaign directed to America's adults needs to be developed.

DENTAL IMPLANTS

Question. There have been some recent feature articles by NIDR and other sources on the status of dental implant technology. As many as 100,000 to 300,000 Americans will undergo surgery to be fitted with dental implants by 1992 compared with fewer than 25,000 done before 1985. What are the risks of the dental implant procedure, and do the benefits exceed the risks in your view?

Answer. As brought out in the NIDR-sponsored NIH Consensus Development Conference in 1988, risks associated with the dental implant procedures may include the possibility of inadvertent perforation of the nasal sinus, local and systemic infection and local

nerve injury, and the possibility of postoperative pain. In addition, it was pointed out that implant placement in children might present special risks, but none was identified. According to the conference participants, dental implantologists routinely consider the possibility of health risks and automatically take precautions to avoid them. The predominant view held by most implant surgeons in regard to health risks is that implant treatment is absolutely contraindicated only in a very small number of patients.

Although there is insufficient long-term evidence comparing the benefits and risks of dental implants, the available reports indicate that implants function well and significantly improve the "quality of life." Therefore, it is my view that the benefits do exceed the risks.

Question. Is the procedure generally safe and effective?

Answer. Information brought out at the conference indicates that carefully planned and placed dental implants--with the appropriate type of implant placed in the appropriate region of the jaw by properly trained, experienced implantologists--are a safe and effective mode of treatment.

Question. Has the procedure been over-sold to the public?

Answer. On the basis of advertisements that I have seen in local newspapers, it seems possible that the dental implant procedure may have been over-sold in some parts of the county. However, the many requests that we continually receive for information on implants both from practitioners as well as potential patients would strongly deny that there has been large-scale overselling. In general, rather than over-selling, there seems to be a hunger for information on dental implants.

DENTAL SEALANTS AND BONDING MATERIALS

Question. New dental bonding materials and sealants are rapidly coming into widespread use. Prophylactic sealing of teeth in younger age groups is increasingly advocated. What is your view on the application of sealants to the biting surfaces of teeth in younger age groups as a way of preventing caries later? Does it really work and is it safe?

Answer. Dental sealants are plastic resins that are applied to the pits and fissures of the chewing surfaces of teeth to prevent tooth decay. Their success lies in their ability to adhere firmly to the enamel surface and to form a physical barrier to prevent bacteria and dietary carbohydrates from creating acids that result in caries. To provide the greatest protection, sealant material should be applied to permanent molars of children and youth between the ages of 6 to 8 and 12 to 14. This schedule corresponds to the eruption pattern of the first and second permanent molars, respectively.

Over the past two decades, dozens of clinical trials have demonstrated the effectiveness and safety of dental sealants. In 1983, the panel of experts for an NIH consensus development conference on sealants concluded that, "The placement of sealants is a

highly effective means of preventing pit and fissure caries. It is safe. It is currently under-used in both private and public dental health care delivery systems." This statement remains true today.

Question. What new materials are coming into practice and what impacts do you think they will have on the general dental health of the public?

Answer. New materials for bonding to both dentin and enamel have led to increased importance of preventive possibilities and more conservative operative dentistry, resulting in less drilling of healthy tooth material to hold the filling. Lower cost alloys as well as higher strength ceramic materials utilizing new handling techniques developed through NIDR-supported research are evident today in dental practice, resulting in costs savings to the patient. Other advances currently under development--such as computer-aided design/manufacture (CAD-CAM) systems, new classes of materials, and new techniques for delivery--will be added to dental practice as soon as they have been perfected and clinically evaluated. These new advances should result in a reduction in treatment time, difficulty, and cost and in greater patient acceptance than with the methods currently available.

FLUORIDATION: SAFE, OR ARE THERE SOME POSSIBLE RISKS?

Question. For years, NIDR has maintained that fluoridation of public water supplies is a safe and effective strategy for preventing caries and has led overall to a 50- to 65-percent improvement in the general dental health of affected populations. However, some critics continue to claim that fluoridation of public water supplies poses some risk to the general public. Have your views on this issue changed since last year? Is there any new evidence that fluoridation of public water supplies can cause cancer, kidney, or other diseases, as some opposition groups continue to claim?

Answer. I can reaffirm our strong endorsement of optimum community water fluoridation as a safe and effective measure, and stress that fluoridation is the most important commitment that a community can make to the oral health of its children and to all future generations. Fluoridation has undergone a nearly constant process of re-evaluation since its inception nearly 45 years ago. Allegations of adverse health effects have been generated by opponents in parallel to public and media interest in specific diseases and disorders, from cancer and kidney disease in years past to the more current charges concerning aging, AIDS, and Alzheimer's. These allegations are investigated as they arise, and none has been substantiated by verifiable epidemiological or clinical data for populations using optimally fluoridated water.

DENTAL PRACTICES AND AIDS TRANSMISSION

Question. Since last year, there has continued to be some general public concern that the AIDS virus can be transmitted via blood and saliva during dental practices. What has NIDR done in the past year to inform the general public and dental practitioner community about this issue?

Answer. Through our information office, we work with the major media to communicate to the general public and health care providers new developments in dental research. For example in the past year, a press release was developed as a result of a study by NIDR researchers who found that human saliva contains a factor that blocks the AIDS virus from infecting cells. This finding may explain, in part, why the disease is not transmitted orally. The results of this study were released to both the lay and professional press to help allay their fears that the virus may be transmitted via saliva.

Regarding the dental profession, the NIDR--in collaboration with the VA, CDC, FDA, and the ADA--is developing an educational package in the form of videos and printed materials on appropriate methods to prevent the transmission of infectious disease, including AIDS, in the dental care setting.

Question. What steps have been taken in the dental practitioner community to minimize the risk of AIDS transmission?

Answer. The dental profession has responded very well to minimize the risk of transmission of AIDS in dental settings. Recent studies show that there has been a dramatic increase in the use of recommended infection control procedures. This is likely a result of many factors, including major educational efforts on the part of organized dentistry, industry, and a variety of government agencies.

Question. How big a problem do you think this issue is?

Answer. The issue is a very important one that requires strict adherence to recommended practices and routine vigilance with regard to compliance over time. Thus, it is important that educational efforts continue to buttress the positive behaviors of practitioners to date and to strive for even better compliance with recommended practices.

Question. What will the $4.3 million request related to AIDS be used for?

Answer. The NIDR will continue to support and conduct research on the oral manifestations associated with HIV infection and on the role of saliva in the transmission or inhibition of HIV and other pathogenic organisms. These objectives will be pursued through research grants, research career development awards, R&D contracts, the intramural research program, and research and management support activities.

Research grants will range from basic laboratory studies on the molecular biology of the opportunistic fungus Candida albicans to epidemiologic studies of large cohorts of individuals at risk for HIV, who are being examined for opportunistic oral lesions and tested to determine sero-status.

Since the role of saliva in HIV infection has not been fully clarified, studies will be devoted to the role of saliva in transmission and will investigate the potential antiviral, non-immune properties of saliva against herpes simplex virus, Epstein-Barr

virus, and cytomegalovirus--all of which have been detected in oral lesions of AIDS patients.

The concentrations of relevant salivary constituents will be determined in the salivas of normal controls and immunologically compromised AIDS patients. The data obtained could contribute to the understanding of the in vivo pathogenesis of recurrent herpesvirus infections in patients without AIDS and provide new insight into the non-immune protective mechanisms of saliva in individuals with other types of severe immunodeficiencies.

Research will be supported on the study of AIDS-associated lesions in HIV-infected hemophiliacs. Investigators will concentrate on growth and development, oral pathology, and microbiology of these lesions.

A collaborative project with the Walter Reed Army Medical Center will be significantly expanded. This study is documenting AIDS-related oral changes with disease progression, changes in oral ecology, and effective treatment of oral conditions. The patient population will exceed 1,000 over the study period.

In the intramural program, research will be expanded on the effects of viruses associated with oral lesions in AIDS patients, and on the functions of oral secretory and nonsecretory epithelial cells.

GENERAL

Question. Are there any other things you would like to say about the NIDR program?

Answer. The major aims of the Institute's research program are the preservation of the health of the oral tissues and the prevention of tooth loss from the chief dental diseases--dental caries and the periodontal diseases--so that the human dentition can last a lifetime. To realize those goals, the NIDR conducts research on the growth, maintenance, and repair of all the orofacial tissues. Studies are conducted on craniofacial development; on the cause, treatment, and prevention of craniofacial anomalies such as cleft lip and palate; on oral tissue genetics and hereditary diseases affecting these tissues; on facial trauma; and on acute and chronic pain conditions. Infections and disorders studied include oral herpes (cold sores), aphthous ulcers (canker sores), papilloma viral and fungal infections, oral cancers, and AIDS.

A few of the recent scientific advances resulting from the research supported and conducted by the NIDR include the following:

Drug development. Anti-cancer drugs: New understanding of how cancer cells move to, and destroy, the membranes separating body organs, thus allowing the cancer to spread, has led to the development of drugs that block specific steps in the invasive process... Chemically modified tetracycline: This version of the drug removes the antibiotic properties but preserves the ability to block the body's production of enzymes that destroy connective tissue. Thus, long-term therapy for periodontitis, arthritis, diabetes, and corneal

ulcerations can be prescribed without fear of inducing antibiotic resistance in bacteria.

Mussel glue. Biotechnology firms have isolated proteins in the adhesive that sea mussels use to adhere to surfaces under water. Genetic engineering methods are being applied to scale up production for potential uses in dentistry and surgery (especially orthopedics) and in the shipbuilding industry.

Diagnosis. DNA probes have been developed that recognize pathogenic and nonpathogenic bacteria in the oral cavity. These probes will sharpen diagnosis, help identify individuals at risk, and aid in basic research on studies of disease processes and host defenses.

Biotechnology. New methods of making human monoclonal antibodies have been developed using blood from normal volunteers. Work continues on isolating and cloning genes coding for proteins essential to the development of teeth.

Human genome. Clones for five major bone proteins have been isolated and sequenced and the chromosomal location of two of these genes completed. The genes are expressed in connective tissue cells and will provide new information about the defects seen in arthritis, Marfan syndrome, osteomyelitis, and osteogenesis imperfecta.

Vaccine development. Animal studies are testing the efficacy of immunization against herpes virus type I and influenza A, using live double recombinant vaccinia virus vectors. A method to synthesize chains of small proteins (peptides) has been developed. As vaccines, these peptides would represent a new class of immune agents well defined chemically and easy to manufacture. If successful they would represent the cleanest vaccine to date, minimizing safety issues that have deterred vaccine manufacture.

AIDS. A factor has been found in saliva that inhibits the ability of HIV to infect immune cells, giving further weight to evidence that there is little risk of transmission of HIV through saliva. Drugs have been identified that block the invasiveness of Kaposi sarcoma cells as well as the ability of these cells to stimulate blood vessel formation. The drugs could be applied locally in patches to the skin or oral soft tissue affected by the cancer.

Restorative materials. A new two-step adhesive bonding system has been perfected based on an earlier multi-step bonding technology. The new system allows a filling to adhere to the tooth, making it unnecessary to drill out healthy tooth material to hold the filling or use an anesthetic. The new system is easier for dentists to apply and increases patient comfort during and after dental treatment.

Sealants. These recently developed materials are applied to the rough pit and fissure surfaces of the teeth of children, thereby protecting these especially vulnerable surfaces from caries. This process--in combination with dentistry's first revolution, fluoridation--has the potential for resulting in the virtual elimination of tooth decay in children.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

PAIN, NEUROSCIENCE, AND BEHAVIOR RESEARCH

Question. Dr. Loe, I understand that the National Institute of Dental Research last year convened an advisory committee to review extramural pain, neuroscience, and behavior research activities at the Institute. Surely some of the most significant pain research being conducted by behavioral and neuroscientists in this country is going on at NIDR. Can you fill us in on some of the details of this valuable review?

Answer. Results of this review concluded that NIDR-supported scientists have played a critically important role in expanding understanding of processes underlying pain modulation and in developing more powerful and safe clinical approaches to pain control. New findings concerning the endogenous opiate system have allowed development of novel drug combinations producing dramatic reductions in post-surgical pain, with lower drug dosage levels and fewer side effects. NIDR-supported neuroscientists have identified neurobiological processes underlying pathological pain and sensory distortions following neural injury; they are developing new approaches to limit neural damage and its harmful effects. Other NIDRsupported researchers have found that sensory input from diverse oral tissues (periodontium, tongue, and tooth dentin) converges on neurons in pain-relaying centers in the brain. These observations help explain the phenomena of poor pain localization and "referred" pain often observed in the oral cavity.

Urgent research priorities remain, however, particularly in uncovering pathophysiological mechanisms underlying chronic orofacial pain conditions, including temporomandibular joint related pain and dysfunction, and in developing more effective means for preventing, diagnosing, and treating these perplexing, often disabling, conditions.

The leadership that NIDR has provided to the Nation's overall pain research effort has provided the basis for more effective pain control, not just in dentistry, but throughout the health-care system.

Question. It also strikes me that NIDR is also an important center for behavioral research into compliance with prevention techniques and treatment regimens. Is this true and can you tell us something about such research?

Answer. NIDR has helped develop very powerful new approaches to preventing oral diseases such as caries and, to a lesser extent, periodontal diseases. However, we recognize that many of these approaches require active participation by patients in preventive regimens and also necessitate some changes in practitioners' behaviors. NIDR recognizes the vital importance of supporting behavioral research in these areas, so that prevention of oral diseases can be improved.

Research includes projects to improve long-term compliance of periodontal patients with effective regular oral self-care. Patients who view their own oral microorganisms through a microscope in a carefully structured sequence of education and periodic feedback are

likely to maintain a disease-prevention regimen. Many general dentists devote minimal time to assessing and charting their patients' periodontal status, but when a relatively brief combined educational/behavioral intervention was instituted, there was significant improvement in dentists' behaviors in these areas.

Recently initiated projects are developing and assessing behavioral interventions to improve oral self care and appropriate dental utilization in seniors, an age group which has not yet shown the major improvements in oral health seen among younger individuals.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

ORAL COMPLICATIONS OF CANCER THERAPIES

Question. Dr. Loe, I understand the NIH recently hosted a conference on the effects of cancer therapy as related to the mouth. What role did the National Institute of Dental Research have in this conference and would you please highlight some of the findings of the conference?

Answer. The NIDR initiated the concept and served as lead sponsor for the recent consensus development conference entitled, "Oral Complications of Cancer Therapies: Diagnosis, Prevention, and Treatment." Co-sponsors were the NCI, the Office of Medical Applications of Research, the NIH Clinical Center, and the Food and Drug Administration. The conference emphasized the critical role of the mouth for the cancer patient during treatment. Evidence is clear that many of the cancer therapies may lead to both life-altering and life-threatening oral complications. It was also shown that these oral complications may have long-term as well as acute sequelae.

An important conclusion of the conference was that there are means available currently to prevent or minimize many of these severe problems. The conference panel recommended that for this reason all cancer patients should have an oral examination and treatment of oral disease before the initiation of cancer therapy and oral care during their treatment. The need for multidisciplinary approaches to this patient group was stressed, with continuous communication between the primary oncologist and the supporting health care team the ideal. Specific recommendations were made regarding the need for prophylactic antiviral treatment to prevent reactivation of herpesvirus in selected patients and for precise therapies of fungal and bacterial infections. A major identified need was to disseminate information concerning oral complications and educate health care workers so that they are using appropriate measures to influence positively the incidence and severity of these complications.

Question. Were there any recommendations or any consensus that developed from the conference that might require any additional dollars in FY 1990 for the NIDR?

Answer. There were several recommendations that could have an impact on NIDR funding. The identification of numerous critical research areas and the distribution of the conference statement should result in an increase in investigator-initiated grant proposals. The need for development and implementation of curricula

to educate health professionals will likely be met through NIDR funding mechanisms. Finally, the formation of a cooperative oral oncology group (along the lines of current regional oncology groups), to sponsor and monitor multicenter protocols studying the incidence and prevention of oral complications arising from cancer therapy, would require Federal funding.

CLINICAL CORE CENTERS

Question. Dr. Loe, if you had the necessary funding for a clinical research center, how would that advance dental research?

Answer. The clinical core centers would build upon existing talents and resources at institutions and centers that are already conducting some clinical research, but are at a disadvantage because of limitations on such items as resources and equipment. Aside from providing state-of-the-art capability, a central focus of the centers would be to create an environment for increased collaboration among basic and clinical scientists, for collaboration between academia and industry, and for the training of new clinical research scientists. Such centers would thus provide opportunities for net accomplishments greater than those currently possible. The principal objective of the NIDR is to promote research that will expedite the translation of basic scientific knowledge into new and better methods for improving the oral health of the Nation. In my judgment, clinical core centers would fill an urgent need to foster multidisciplinary clinical, applied, and basic research and to supply the technical resources to conduct research at the level of sophistication required to achieve this goal.

Question. Could a clinical research center help the dental schools in Pennsylvania work with private industry to transfer research findings to clinical applications?

Answer. Yes; the private sector has an important role in the expeditious transfer of developments in dental research to clinical applications for the well-being of the general public. Clinical core centers would provide an excellent vehicle for industry, the academic community, and the NIDR to collaborate on bringing to fruition the advances in science and technology for the benefit of the patient population. Although government funds cannot directly support industrial programs, industry can financially support and scientifically participate in collaborative efforts with the dental schools in the research activities of clinical core centers. Clearly, many research developments have reached the stage where both academic and private sector expertise are essential in order to expedite transfer of research for the benefit of the profession and the public.

TMJ DISORDERS

Question. Dr. Loe, recently there has been a series of reports regarding temporomandibular dysfunction (TMJ). Would you please provide the latest findings on TMJ, and specifically how it affects people?

Answer. The NIDR has funded several multi-year epidemiological studies examining adults in the general population as well as persons with "signs" of TMJ disorders (e.g., "clicking" in the jaw; tenderness in jaw muscles) or with complaints of jaw pain. Initial

results indicate that up to 12 percent of the general population reports episodes of substantial jaw pain over a 6-month period, and up to 60 percent show at least one "sign" associated with TMJ disorders.

Studies have also shown that most patients seeking treatment for TMJ problems are in the 20- to 40-year age group. Females seek treatment three times more frequently than males; however, this may occur because studies show that women are more inclined than men to seek dental care.

Although there is no consensus among dental researchers as to which symptoms actually constitute a TMJ disorder or condition, the most clinically proven symptoms are the following: pain and tenderness in the chewing muscles and in the temporomandibular joint; limited movement of the jaw; clicking or popping sounds in the jaw when opening and closing the mouth; and radiating pain in the face, neck, back, or shoulders.

Question. Has research determined an appropriate treatment for TMJ?

Answer. Unfortunately, the information base on research data on treatment for TMJ disorders is not sufficient to determine appropriate measures at this time. This point was clearly brought out at an NIDR meeting that considered new diagnostic approaches to orofacial pain, including discussions on TMJ disorders.

We plan to stimulate additional basic research on the etiologies underlying TMJ disorders as well as clinical studies on the characteristics of TMJ symptoms over time and on patients' response to alternative treatment approaches.

Ongoing epidemiological studies suggest that the majority of persons with TMJ symptoms, whether or not they are treated, do not get worse over time. But an estimated 20 to 25 percent do show continuing or increasing disability. We need a much better understanding of how to differentiate such patients early, so they can receive treatment early.

NIDR-supported scientists have discovered that anti-depressant medications can relieve symptoms in some patients and that problems with occlusion are not, overall, a major predictor of TMJ problems.

National Institute of Diabetes and Digestive and Kidney Diseases

STATEMENT OF DR. PHILLIP GORDEN, DIRECTOR

SUMMARY STATEMENT

Senator Harkin. Let us now go to the National Institute of Diabetes, Digestive, and Kidney Diseases.

Dr. Gorden. Thank you, Mr. Chairman.

NIDDK programs are united by many common threads involving basic and clinical research. The kidney disease of diabetes mellitus is the leading cause of end-stage renal disease. We have mounted a major program to find an effective treatment for this devastating problem.

The Diabetes Control and Complications Trial is a large clinical trial, designed to test methods of preventing the complications of diabetes.

We have just begun a large-scale clinical trial on the modification of diet in renal disease, a study to test the efficacy of a low-protein diet to forestall the onset of end-stage renal disease.

Extensive basic research has now permitted the biotechnology industry to produce the truly miracle drug of erythropoietin, which prevents the devastating anemia associated with end-stage renal disease, and permits better rehabilitation of our patients.

Our endocrinologists have developed effective methods of treating the hypothyroidism of Graves' disease and have extended these therapies in effective ways to such disorders as thyroid cancer.

Obesity affects an estimated 34 million Americans, and is a major risk factor for life-threatening diseases. We now understand that genetic factors may control how calories are burned in an individual, and special efforts are now being focused on why weight loss is so difficult to maintain.

NIDDK-sponsored studies of the human genome have given us new insights into such important problems as cystic fibrosis, polycystic kidney disease, and a whole host of rare orphan diseases.

Liver transplantation has now become a major treatment modality for end-stage liver disease. We have developed at least three nonsurgical treatments for gallstones. Inflammatory bile disease remains a major challenge. But we have done much to decrease the mortality of this devastating problem. Through our digestive disease centers, and a series of basic studies, we are attempting to better understand and treat both forms of this disease: Ulcerative colitis and Crohn's disease.

Collectively, these advances demonstrate the enormous power that today's technologies bring to our continuing quest to understand and treat human disease.

PREPARED STATEMENT

Mr. Chairman, the fiscal year 1990 budget request for this Institute is $577,235,000. I would be very pleased to answer any questions that you may have.

[The statement follows:]

STATEMENT OF DR. PHILLIP GORDEN

I am pleased to share with you some of the recent achievements resulting from research supported and conducted by NIDDK. For more than three decades, NIDDK has led the Nation's research efforts to combat many of our most pressing health problems: diabetes, endocrine, and metabolic diseases; digestive and nutritional disorders; and kidney, urologic and blood diseases. As key participants in the biotechnology revolution, Institute-funded researchers are uncovering the causes of many debilitating diseases, developing better methods of diagnosis and treatment, and finding clues to possible disease prevention.

NIDDK programs are united by many common threads involving very basic and clinical research. For example, our genetic studies are pinpointing genetic defects for cystic fibrosis, Tay-Sachs disease, polycystic kidney disease and diabetes, and in turn, these studies are making enormous contributions to our understanding of the human genomic map. A recent example is the mapping of the androgen receptor on the X chromosome, an advance that should provide important insights into abnormal growth of the prostate. Other cross-cutting research is the application of chemistry to drug development. Taking advantage of a rapidly developing base of knowledge about drug receptors, our chemists have designed drugs that can block the PCP receptor and are highly effective in animals in preventing permanent brain damage after stroke or head trauma. We are also defining the chemical processes involved in the frequently fatal coma that accompanies serious liver disease; this knowledge should aid in the design of new drugs for this condition. Integral to our intramural division, as well as all of our programmatic extramural divisions, are ongoing projects in AIDS research. This research takes special advantage of our expertise in structural biology, urology, blood diseases and inflammatory bowel diseases.

The mystery of diabetes is beginning to unfold. Affecting about 11 million Americans, this disease places an enormous strain on public health resources, with an annual cost of over $20 billion. The various forms of the disease involve immunologic, genetic and cell-signaling defects, and considerable progress has been made in all these areas. In insulin dependent diabetes, the immune system destroys the insulin-producing cells. Markers have been identified that signal the impending disease years before it is fully manifest, allowing for the possibility, in the future, of early intervention. Further, in a major discovery, our grantees have pinpointed in an important membrane protein, a single amino acid that confers susceptibility to or protection from the immune attack. These studies offer great hope for predicting and preventing this disease process in susceptible people.

Progress has also been made in the puzzle of noninsulin-dependent diabetes. In this form of the disease, cells fail to respond properly to insulin, even when adequate levels are present in the body. Powerful techniques of molecular biology are revealing the precise character of molecules that regulate glucose metabolism, such as insulin, the insulin receptor, and the glucose transporter. Scientists are also identifying other molecules, so-called "second messengers," that interact at later stages in this extremely complex process. Understanding how these molecules work

and interrelate could pave the way to the design of therapies aimed at blocking or enhancing their action.

Diabetes takes a heavy toll on minority populations, including Blacks, Hispanics, and Native Americans. The Institute is currently sponsoring a series of conferences to chart new research directions to address this problem. We already support the world's largest prospective study of non-insulin dependent diabetes at our field station in Phoenix, Arizona, which has contributed a wealth of knowledge about the causes, epidemiology, and clinical course of diabetes in Pima Indians. Our investigators have identified a very early defect in muscle resistance to insulin and a series of subsequent steps leading to full blown diabetes. These studies have important implications for other minority populations who are also disproportionately affected by the non-insulin dependent form of this disease.

Drug development efforts are rapidly expanding treatment potentials for diabetic complications. Two drugs--aldose reductase inhibitors and aminoguanidine--may provide therapies for diabetes-related damage to nerves and connective tissue. Clinical trials have suggested that aldose reductase inhibitors may prevent nerve damage, as well as restore function to already damaged nerves. Another vital component of the Institute's multifaceted diabetes research program is the Diabetes Control and Complications Trial (DCCT), a major clinical trial of 1,400 patients with insulin-dependent diabetes. This study will demonstrate the effects of two insulin treatment regimens on blood glucose levels and on early damage to blood vessels, a serious complication of diabetes. Recently, the trial has also begun to look at the development of kidney complications of diabetes.

The endocrine system plays a role in virtually every biologic process, and is a key to understanding and treating many diseases such as cancer, osteoporosis and prostatic enlargement. Using new molecular techniques, researchers have identified and cloned cell receptors for a host of molecules--such as vitamin D, an important bone-regulating factor, and the male hormone, androgen. This year, investigators found the first evidence of estrogen receptors on bone cells. These results may help explain how estrogen protects women from age-related bone loss. Endocrine research is also shedding light on the secretion of parathyroid hormone, a primary regulator of body calcium. From these studies, clues may be found to such diseases as osteoporosis, in which calcium plays an essential role.

The Institute supports extensive research on orphan diseases including a wide range of metabolic abnormalities. Researchers have developed a new form of enzyme replacement to treat children whose immune systems fail to protect them against disease because of an inherited enzyme deficiency. This approach, which involves chemically altering an enzyme, may provide a model for the development of new drug therapies for other metabolic diseases. In another orphan disease, cystinosis, grantees have reported a new test to identify carriers, thereby improving on current, less accurate tests. In cystic fibrosis, researchers are very close to identifying the defective gene, a discovery that will ultimately permit scientists to determine its function, improve diagnosis, and devise better therapies. This technology is already used extensively in prenatal diagnosis. Researchers are also making

strides in characterizing the defect in chloride ion transport now known to be present in the cells of cystic fibrosis patients. We are greatly encouraged by recent progress in all these areas.

Chronic digestive diseases exact an enormous toll on this country in terms of lost wages and medical costs. Our intramural and extramural scientists have made major inroads into developing effective anti-ulcer therapies. New techniques, such as fiber optic endoscopy, have also enabled physicians to gain direct access to bleeding ulcers for more rapid and effective treatment. Research into the immune system of the gut is providing much needed information about many digestive diseases including the inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, as well as AIDS. NIDDK, as well as other NIH institutes, has made essential contributions to understanding the course and treatment of chronic viral hepatitis. This strong base of fundamental and clinical research was an important precursor to the recent discovery by industrial scientists of the causative agent in non-A, non-B hepatitis. These collective discoveries will have important implications for the prevention and treatment of this severe, chronic liver disease. Hope is also emerging for patients with primary biliary cirrhosis, a liver disease that is the largest single reason for liver transplantation. Pilot studies of several promising drugs--colchicine, methotrexate and a bile acid--are now under way. Recent years have witnessed the development of several nonsurgical approaches to treating gallstones, which affect about 20 million Americans and disproportionately afflict minority groups. Physicians can now treat some patients with shock-waves, with stone-dissolving drugs, or with a combination of such drugs and shock waves.

Liver transplantation is a life-saving treatment for which one-year success rates now range from 70 to 90 percent in leading transplant centers. The Institute has supported pioneering research on liver transplantation for over 20 years and has contributed to increased understanding of transplant biology, such as the use of cyclosporin to suppress organ rejection. Recently, NIDDK grantees devised a new solution for prolonging the viability of harvested organs for longer periods of time than previously possible. To help address the many unanswered questions in this field, NIDDK supports three research resources: a liver transplantation data system, a liver tissue procurement and distribution system, and a liver cell culture facility.

Studies in nutrition and metabolism are defining obesity, which affects an estimated 34 million Americans and is a risk factor for life-threatening diseases. Intramural studies have recently helped determine the parameters of normal metabolism and the causes of variability in metabolic rates. Identification of a group of "fuel efficient" individuals who are prone to weight gain suggests that a genetically predetermined defect may underlie some forms of obesity. Additional studies of this kind are under way in dieting obese patients at our obesity and clinical nutrition research units. These studies are attempting to clarify the mechanisms involved in the all-too-frequent weight gain that follows an initial period of successful dieting. Other genetic and biochemical studies have uncovered a possible signaling molecule, called adipsin, that may regulate energy balance and may be a marker for some forms of obesity. This avenue of research may ultimately reveal the

molecular basis of fat storage. Because abdominal fat is more predisposing to serious illness than is fat on the hips, the control of fat distribution is another important line of research. The Institute wants to build upon and intensify research on risk factors for obesity in the hope of finding ways to prevent this serious health problem.

End-stage renal disease (ESRD) is one of this country's most serious public health problems, costing the Federal government nearly $3 billion annually for dialysis and transplantation under Medicare. Research has shown that the kidney's blood filtering rate is an early indicator of kidney disease in diabetics, who comprise a large and growing component of the ESRD patient population. We also know that diabetes-related kidney damage in animals may result from increased capillary pressure in the kidney and that special types of blood-pressure-lowering drugs can completely counter this effect. Studies are now under way in patients to test the therapeutic benefit of these drugs in kidney disease of diabetes mellitus.

A clinical trial, "Modification of Diet in Renal Disease," which is designed to test the effect of protein and phosphorus restriction on the progression of chronic renal disease, is now in full operation with support from this Institute and the Health Care Financing Administration (HCFA). In another collaborative effort with HCFA, the Institute has established a U.S. Renal Data System that should provide insights regarding the mortality and morbidity of ESRD and provide a data base for designing prospective studies. In urology, the Institute is working to build a high quality research program, which will address such important problems as benign prostatic hyperplasia, interstitial cystitis, and diabetes-related bladder disease.

We have previously reported on the extensive basic research leading to the discovery and cloning of the gene for erythropoietin, a red blood cell growth factor, and the production of this hormone through genetic engineering. During the past year, these biotechnology advances have permitted large scale production and use of a synthetic form of this human hormone in patients with ESRD. Patients treated with this drug have shown rapid recovery from anemia and remarkable rehabilitation, without negative side effects, and the drug is now under investigation in other forms of anemia. In other studies of blood diseases, investigators are exploring how the body shifts hemoglobin production from the fetal type, found very early in life, to the adult form. The control of this hemoglobin "switch" may one day provide a new therapy for sickle cell anemia and thalassemia by making it possible for patients to produce the beneficial fetal hemoglobin throughout life.

Many of the discoveries I have described today will lead to more effective therapies for patients afflicted with some of our Nation's most serious diseases; others are helping to depict highly complex biologic processes essential to health. Collectively, these advances demonstrate the enormous power that today's technologies bring to our continuing quest to understand and treat human disease.

Mr. Chairman, the FY 1990 budget request for this Institute is $577,235,000. I will be pleased to answer any questions you may have.

BUDGET REQUEST

Senator HARKIN. How much would that increase over last year?
Dr. GORDEN. That is a 3.7 percent increase.

GALLSTONES

Senator HARKIN. Here is one that I cannot believe we have not done something about. But between 10 and 15 percent of adult Americans, or approximately 20 million people have gallstones in America. There are 500,000 gallstone surgeries each year. The Nation's most frequent surgical procedure I found out. I did not know that.

Mayo Clinic researchers have won patent approval for a compound they contend can dissolve stones in less than a day.

What can you tell us about this?

Dr. GORDEN. It is a new therapy that has been developed by one of our grantees, as you mentioned, at the Mayo Clinic.

It is a solvent. It is basically an ether compound that can be instilled directly by a small catheter into the gallbladder. Usually, the treatment requires approximately 3 days, in which you constantly lavage, put in and take out, this solution. Basically, it dissolves specific types of gallstones. The recent clinical trial that was just reported in the New England Journal of Medicine this year, proves this to be a highly effective approach.

Senator HARKIN. Is it being widely disseminated?

Dr. GORDEN. At this point, it is coming out of its very early-phase studies, and I would anticipate that this technique would be disseminated widely over a very short period of time.

Senator HARKIN. This was about 1 year ago, when they first came out with this, and now it is about 1 year later. Does it require FDA approval or anything like that?

Dr. GORDEN. This falls into a category that will require FDA approval, and that will be certainly pending for this particular material.

Senator HARKIN. Do we know of any complications, anything else, any other side effects?

Dr. GORDEN. There have been minimal complications from the solution itself. There are some mild complications associated with the procedure. But I think that, as one gains more experience with the procedure itself, they will be overcome.

THYROID CANCER

Senator HARKIN. I am interested in thyroid cancer, and things affecting the thyroid. Again, are we making good progress on that? I understand the mortality rate is going down all the time on thyroid cancers.

Dr. GORDEN. Yes, sir; that is certainly true. It is one of the cancers in which there has been a decrease in mortality. We believe that is due to effective forms of treatment that have been developed over the last several years, which include radioactive iodine delivered in appropriately prescribed ways.

Also of benefit are several types of adjunctive therapy that enhance the radioactive iodine, which is a primary treatment modality for this disorder.

END-STAGE RENAL DISEASE

Senator HARKIN. One of the other things that we fund out of this subcommittee is programs through Medicare. Dialysis treatment for end-stage renal disease, an entitlement of Medicare, costs us $2.5 billion a year, four times the cost of all the research in your Institute. This is a direct cost to the Federal Government, which I believe should give added emphasis to carrying on end-stage renal disease research. What progress is under way, and when can we expect any results? Do you have any idea on that?

Dr. GORDEN. There are many different points of attack. End-stage renal disease or ESRD, results from, essentially, a whole host of diseases that affect the kidney to the point where it ceases to function.

As I mentioned, the leading cause is diabetes, and we have several programs designed to attempt to prevent kidney disease complications in diabetic patients. Treatment of hypertension is another major goal in an attempt to alleviate ESRD.

We have just begun a clinical trial, based on the hypothesis that lowering the amount of protein in the diet will forestall, or perhaps prevent, end-stage renal disease in susceptible individuals. We are assessing whether individuals who have begun a decline in kidney function can be protected against further decline by decreasing their protein intake. That is an observation that has been made in experimental animals. Now, we have begun a full-fledged, multicentered clinical trial to test that hypothesis in patients. Should that trial be successful, I think it will have a very major impact on ESRD—not only on the well-being of many people, but also on the enormous cost that you have referred to.

CYSTIC FIBROSIS

Senator HARKIN. Senator Reid.

Senator REID. Thank you, Mr. Chairman.

Tell me what is happening with cystic fibrosis. One of our neighbors has cystic fibrosis, and of course, there has been a lot written based on the book that father wrote about his child.

Is anything good happening in that regard?

Dr. GORDEN. Yes; I think it is one of the really exciting areas, both at the clinical level and the basic research level.

First of all, the children with cystic fibrosis are living much longer. Just a few years ago, it was very rare for a child with cystic fibrosis to get out of the teenage years. Now, this longer life expectancy is common.

I think the dramatic thing that has really driven this field is research that has been sponsored by our Institute, and the National Heart, Lung, and Blood Institute, which has permitted the mapping of the genetic locus for the cystic fibrosis gene.

We know it is a specific, genetic defect. We know a lot about this gene, and the gene has been mapped. We are getting very close to actually isolating the gene itself, which would permit important

studies in experimental animals and a variety of other research. This is an extremely important way to approach genetic diseases.

The second thing that has happened is that one of our intramural scientists was one of the first to elucidate the actual defect. It was shown 25 years ago that children with cystic fibrosis had an excessive amount of salt in their sweat, an excessive chloride concentration. Even today, this is the central diagnostic test for this disease. We now understand the fundamental reason why that is true. We know that there is a defect in a particular kind of pump, called the chloride pump, and we are beginning to understand the pieces that make up that pump. If we can work in both directions—from the gene locus and from the chloride pump defect—I think that this will permit a very rapid pace in combating this disease.

So, I think there is a great reason to be optimistic about the pace that this research has moved in the last several years. I say this with great caution, however, because this is a very serious disease.

FUNDING FOR DIGESTIVE DISEASES RESEARCH

Senator REID. Doctor, I appreciated your statement in your abbreviated testimony here today regarding chronic digestive diseases, and the fact that they do exact a tremendous toll on the country in terms of people being sick. And in your longer statement you indicate here—in terms of lost wages and medical costs.

As I see the budget that you have requested, it is over a $21 million increase—3.7 percent. But yet, in these diseases which deal with, among other things, Crohn's and ulcerative colitis, there is a decrease. At least that is information I have—is that true?

Dr. GORDEN. I do not think there is a real decrease. I think there is a slight fluctuation from year to year having to do with the expiration and award of particular grants. So, at any one point in time, when one actually looks at the dollar figure, it may be slightly more, or slightly less. The average figure for inflammatory bowel disease is basically a constant from 1988 to 1989.

Senator REID. The decrease, my staff tells me, is in the amount of grants. And you have indicated that that is simply from the fact that some of them are not being renewed, but they are in the mill, so to speak. Is that right? Did I perceive it right?

Dr. GORDEN. With respect to a specific category, our total number of research project grants——

Senator REID. In this category.

Dr. GORDEN. Support for this category of research will remain constant, with the exception of the normal fluctuation that goes on between the end of a grant and the beginning of another.

Senator REID. And the dollar amount will remain fairly constant?

Dr. GORDEN. The dollar amount will remain fairly constant.

Senator REID. Because the funding for these NIH Core Research Center grants, which is primarily devoted to Crohn's and ulcerative colitis, I am told, is cut 25 percent.

Dr. GORDEN. Yes, sir; we have 12 digestive disease centers, and we have one devoted very much to inflammatory bowel disease. The overall reduction for our 12 centers is a 25 percent reduction

from their study section approved levels. The research project grants are cut by a factor of 10 percent also.

Senator REID. And why is that?

Dr. GORDEN. That is because there simply is not enough money to support these grants at the study section approved level.

Senator REID. Even though there is a $21 million increase in your budget?

Dr. GORDEN. Yes, sir; essentially, our center's budget has been virtually held constant for the last 2 or 3 years.

Senator REID. And it will not change, even though—or at least your submission will not change, even though there has been an increase of $21 million?

Dr. GORDEN. No, sir.

Senator REID. Where are the increases going, if they are not going to these digestive diseases?

Dr. GORDEN. The $21 million goes predominantly into our research project grant category, and very small amounts go into other areas, such as our intramural program. Nearly 85 percent of the $21 million increase that you refer to will go into our research project grants. Even at that, we will be reducing the number of new and competing research project grants by about 140, from 1989 to 1990.

Senator REID. I guess I am having trouble understanding that support. Having increases, why are we having all the cuts?

Dr. GORDEN. I think that, fundamentally, it has to do with the inflation factor in biomedical research.

Senator REID. I see. What you are saying is—you have the same number of grants, just less dollars for each grant?

Dr. GORDEN. From 1989 to 1990, we will actually take a reduction in numbers of grants. And that is virtually totally based on inflation. If we add up our noncompeting costs—that is, our obligated costs—and look at our 1990 budget, we simply do not have enough money to pay for more than 400 plus new and competing grants, which is approximately 140 fewer than the 1989 level.

Senator REID. Again, Dr. Gorden, and I am certainly not trying to be argumentative. I am trying to understand what we are talking about here.

We are increasing $21 million. Is that going to salaries, and things of that nature?

Dr. GORDEN. Within the grant category, your question relates to what leads to that inflation?

Senator REID. Yes; overall, a 3.7-percent increase.

Dr. GORDEN. The biomedical research deflator, or inflation level is somewhere close to 6 percent.

Senator REID. You are saying 6 percent would allow you to tread water?

Dr. GORDEN. Yes.

Senator REID. And you are not treading water, you are going backwards?

Dr. GORDEN. Yes.

Senator REID. Even though this is a 3-percent increase it is not allowing you to keep up with inflation?

Dr. GORDEN. Yes, sir.

Senator REID. Thank you, Mr. Chairman.

Senator HARKIN. Senator Bumpers.

CYSTIC FIBROSIS

Senator BUMPERS. I have a couple of questions. Are you going to have approved clinical trials for cystic fibrosis that you are not going to be able to fund?

Dr. GORDEN. We will basically not be able to fund any new clinical trials in fiscal year 1990, that's correct.

Senator BUMPERS. That would be good and that you would like to fund?

Dr. GORDEN. Yes; and we have approximately 15 clinical trials that we have actually listed that would be high-priority clinical trials.

Senator BUMPERS. What would it cost you to fund those, doctor?

Dr. GORDEN. It would cost about $17 million.

Senator BUMPERS. Are we talking about cystic fibrosis?

Dr. GORDEN. No, sir; we are talking overall.

Senator BUMPERS. Do you know how many of those would be cystic fibrosis?

Dr. GORDEN. We don't have any proposals for clinical trials in cystic fibrosis at this time.

RENAL DISEASE

Senator BUMPERS. How about renal disease trials?

Dr. GORDEN. In the area of renal disease, these trials would relate to a major area of end-stage renal disease in which we are trying to inaugurate studies. They also relate to several other areas of gastrointestinal diseases, such as gallstone formation.

LIVER TRANSPLANTATION

Senator BUMPERS. One final question, Dr. Gorden, and that is you say that liver transplants among the centers who have been in this business for some time have a success rate of 70 to 90 percent, and I know that Medicare will fund all end-stage kidney transplants, but Medicare's policy on live transplants is very restrictive.

If the success rate for liver transplants is 70 to 90 percent, they are not really experimental any longer, are they?

Dr. GORDEN. I think that there are a number of disease categories in which transplantation clearly is not experimental in a general context. There are several other categories for which some controversy may exist about the longer term efficacy of the procedures. For instance, one of the major concerns is whether, in alcoholic liver disease, one can do liver transplantation successfully over the longer term. Just this past year one of the major transplant centers in Pittsburgh has reported a fairly sizeable number of patients who have done exceedingly well. While their success rates don't quite approach the numbers you quote, they are approaching an acceptable level of survival of the graft and of the patient.

I think what is happening is that when one gets more experience with this procedure, it is done better, and techniques improve. Just within the past 1½ to 2 years, our grantees have developed a solu-

tion that permits preservation of livers to be transplanted for over 24 to 36 hours. That is a dramatic increase, because frequently these transplantations had to be done in the middle of the night under very inopportune circumstances because of liver preservation problems. That new solution makes an enormous difference. When you introduce a technology such as that, it opens up the application of transplantation to a lot of other diseases for which it simply wouldn't have been appropriate previously. So, I think this area will have to be reevaluated on the basis of the present success rate and the new technologies that have been introduced.

Senator BUMPERS. Thank you, Mr. Chairman.

Senator REID. Mr. Chairman, can I ask one additional question?

Senator HARKIN. Yes.

Senator REID. Before Senator Bumpers leaves, Senator Bumpers, I think that your statement was very probative. All these things about which we have a concern in this area dealing with diabetes, digestive, and kidney diseases, all the research that they want to do at the National Institutes of Health in this regard they could do it for $20 million which would bearly keep up with inflation. I think we as a Congress should look closely at that. I think if we cannot make a case for some of these programs, then that does not speak much for us.

Senator BUMPERS. If they could figure out some way to make these projects explode, we could probably get the money for it. [Laughter.]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you. We will have some additional questions which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

GALLSTONES

Question. Between 10 and 15 percent of adult Americans or approximately 20 million people in the United States have gallstones. While there are half a million gallstone surgeries each year -- the nation's most frequent surgical procedure -- Mayo clinic researchers have won patent approval for a compound that they contend can dissolve stones in less than one day. Doesn't this eliminate the need for surgery?

Answer. We've seen several alternative medical therapies developed for dissolving gallstones in recent years. The first of these approaches involves taking bile acids orally. Bile acid therapy works best on small cholesterol gallstones. An important adjunct to this therapy is ultrasonic shock-wave lithotripsy, presently the subject of active clinical and laboratory research. The third treatment involves dissolving cholesterol gallstones with methyl tert-butyl ether (MTBE). This therapy can be lifesaving in patients with symptomatic, complicated gallstone disease who are poor candidates for general anesthesia or surgery. These three treatments can be used together to overcome disadvantages inherent in any individual therapy. For instance, large stones can be fragmented into small stones, which can then be dissolved more rapidly with either bile acids or MTBE.

For the present, due to the high rate of gallstone recurrence, surgery to remove the gallbladder remains the standard treatment for gallstones. Nonetheless, the considerable progress made in the development of these nonsurgical therapies now provides patients and their physicians alternative choices.

Question. What is NIDDK doing to help educate the public and the medical community so we can eliminate this unnecessary surgery?

Answer. At the present time, surgical removal of the gallbladder is the standard treatment recommended for any patient with symptomatic gallstone disease. Several therapeutic approaches, however, now show promise as important alternatives to surgery. These include dissolving gallstones through direct infusion of a form of ether into the gallbladder or dissolving stones with bile acid, used alone or in combination with shock-wave therapy.

The focal point for dissemination of information and education materials relevant to the latest treatment options in digestive diseases is the NIDDK-supported National Digestive Diseases Information Clearinghouse. The clearinghouse seeks to increase knowledge and understanding about digestive diseases among patients, health professionals, and the public and acts as a catalyst in assisting these groups in the development and exchange of educational materials. In addition to answering public inquiries, the clearinghouse distributes fact sheets, booklets, and other lay-oriented materials on a variety of digestive diseases; produces a directory of digestive disease organizations; a bibliography of digestive disease patient education publications; a digestive diseases glossary; and a catalog of audiovisual

materials. A booklet produced by the clearinghouse addresses the causes, symptoms, diagnosis, and treatments for gallstones, including non-surgical alternatives.

In addition, the National Digestive Diseases Advisory Board of the NIDDK has a responsibility to advise and make recommendations concerning the effective applications of existing medical knowledge to the Congress, the Secretary of Health and Human Services, the Directors of the NIDDK and the NIH, and heads of other Federal agencies.

CANCER OF THE THYROID

Question. Dr. Gorden, as you know, my brother has cancer of the thyroid gland and has been treated at NIH for this condition. The overall incidence of thyroid cancer is about 10,000 cases annually with a 10 percent mortality rate. Most thyroid cases are not fatal and even those that cannot be treated tend to progress very slowly. Is that correct?

Answer. That information is generally correct. Of course, for certain specific types of thyroid cancer, or for cases where a tumor is well advanced before discovery, the situation may not be as hopeful. For instance, while papillary carcinomas usually have a very good prognosis, a rare form, called the "tall cell variant," is more likely to spread and is more difficult to treat. The prognosis in any given case, however, depends on the specific circumstances of the case and the response of the individual to treatment. Only a patient's physician has all the information to make projections about his or her condition.

Question. What are the most effective treatments for thyroid cancer?

Answer. Treatments may vary, depending upon which type of cancer it is, the degree of metastasis, and whether or not alternative treatments have failed. In general, the initial treatment is surgical removal of the tumor and frequently of the entire thyroid gland. In cases where the tumor has spread beyond the gland, however, it may not be possible to remove all the cancer.

As a follow-up to surgery, thyroid hormone is usually administered. This treatment is used for two reasons. First, if the thyroid has been completely removed, the patient needs an outside source of thyroid hormone to survive. Second, thyroid hormone has the effect of suppressing the growth of residual tumor cells if the tumor is well differentiated and still retains the characteristics of thyroid tissue.

Alternatively, radioactive iodine may be used to treat thyroid cancer. Because the thyroid is able to take up and concentrate iodine, very high doses of this radioisotope can be delivered directly to target thyroid carcinoma cells. Sometimes, however, tumors may change so much from their original forms that they no longer respond to hormones or take up iodine. In these cases, external radiation may play a role in treatment. Chemotherapy is sometimes employed, but most cases respond only partially.

Question. What research opportunities are there for improved treatment of this disease?

Answer. I see a number of opportunities here for research. To begin with, while chemotherapy alone has not proven too successful, certain chemotherapeutic agents can serve as radiation enhancers. It may be possible to use these drugs to enhance radioactive iodine therapy. An example is the drug Adriamycin.

Another area where research is needed is in the development of guidelines for the use of radioactive iodine therapy. While this therapy is clearly indicated in many severe cases, for milder cases we don't know at what point the risks of radiation exposure outweigh the benefits.

We also have an animal model of thyroid cancer that can be used to test other treatments -- a population of rats that bear transplanted thyroid tumors. Certainly, in general, we also aim to develop more effective chemotherapeutic agents and immune therapy.

Question. I understand that Mrs. Bush's treatment for Graves' disease really involves an overactive thyroid gland. How common is Graves' disease, and how adequate are current treatments for the disease?

Answer. Graves' disease is a common disorder which affects women seven times more frequently than men. The prevalence of Graves' disease in the United States is uncertain, but has been estimated to be 0.4 percent. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is supporting a thyroid component of the National Health and Nutrition Examination Survey. This study is now in progress and will provide important data on the prevalence of conditions in which the thyroid gland is overactive or underactive.

You are correct that Graves' disease involves an overactive thyroid gland. The two major approaches to the treatment of Graves' disease are directed at limiting production of thyroid hormone. Drugs are available which chemically block hormone synthesis, and are effective in controlling the disease. However, when these drugs are discontinued, the thyroid hyperfunction usually recurs. The second approach to therapy involves permanent destruction of thyroid tissue, which is achieved with radioactive iodine or surgery. Radioactive iodine treatment is safe, effective and economical, and avoids the complications of surgery. Amelioration of hyperthyroidism usually occurs several months after therapy, and medical therapy can control symptoms during this period. Frequently permanent hypothyroidism, or inadequate thyroid hormone production, results from thyroid damage from the radioactive iodine. This is treated easily and effectively with long term administration of thyroid hormone. Occasionally hyperthyroidism recurs and a second dose of radioactive iodine is required.

Graves' disease is a multi-system disorder. In addition to thyroid dysfunction, patients with Graves' disease may have eye and skin problems. Occasionally the eye involvement may be severe and may require specific therapy for protrusion of the eyes, involvement of ocular muscles, or inflammation.

END STAGE RENAL DISEASE

Question. Dialysis treatments for end-stage renal disease are an entitlement out of the Medicare Trust Fund that cost us over $2.5 billion each year or more than four times the cost of all research funded by your institute. This is a direct cost to the federal government which I believe should give added emphasis to carrying on end-stage renal disease research. What research progress is underway, and when can we expect some results?

Answer. There are a number of programs that are underway in the area of dialysis treatments for end-stage renal disease. The programs are specifically designed to address the epidemiology, causes, prevention, and more appropriate treatment.

We have established the United States Renal Database System (USRDS) for the specific purpose of conducting biomedical research into the causes, complications, and best means to manage end-stage renal disease. This is a collaborative effort with the Health Care Financing Administration (HCFA), which is providing all of the data through their end-stage renal disease networks. Utilizing their special expertise in economics and financing, they will be conducting cost-effectiveness studies on the same group of patients. Together we will provide, for the first time, a comprehensive study on the end-stage renal disease population. The USRDS was established in 1988 and is now functioning. The first set of biomedical studies has been approved by the Scientific Advisory Committee and will start in FY 1989.

Data from HCFA files have been assessed and there have been a number of new concepts that have emerged. In the area of hypertension: the incidence of hypertensive end-stage renal disease in the U.S. is high and increasing; the incidence of this complication is therefore not being affected by the current treatment for hypertension; the incidence of this complication in blacks between the ages of 25-65 ranges from 10-20 times that in non-blacks.

Another program underway is research related to Kidney Disease of Diabetes Mellitus (KDDM). The incidence of end-stage renal disease is increasing at an annual rate of 2 percent. KDDM is now the largest single cause of end-stage renal disease in the United States. It now represents 32 percent of all new patients entering into end-stage renal disease treatment. We have mounted two programs in this area, and are planning a third. We have a total of 27 grants in the area of KDDM.

AIDS is a growing problem especially in the black population. The NIDDK has funded 4 grants totaling $1.1 million. These studies have already provided evidence that passively infected children have an increased incidence of end-stage renal disease, especially in blacks.

The George O'Brien Centers were authorized for the specific purpose of studying the causes and means to interrupt the progressive decline in kidney function that leads to end-stage renal failure. These studies provide centers of excellence in the study of the causes and prevention of end-stage renal disease at a very fundamental basic scientific level. It is too early to expect results from these efforts.

The congressionally-mandated Modification of Diet in End Stage Renal Disease (MDRD) study is now in the clinical trial phase, after having devised and tested the protocol. There are approximately 800 patients and the cost is $45-50 million over an 8 year period. The first phase began in 1984. The clinical testing phase has just begun. However, during the feasibility phase we obtained evidence that the effective control of blood pressure, perhaps at levels lower than ordinarily specified, provides some additional protection against the rapid decline of renal function in patients with established chronic renal disease.

The management of end-stage renal disease complications program provided the support for the development and testing of erythropoietin in the management of the most devastating complication of end-stage renal disease, namely anemia. It is too early to say whether or not this marked improvement in patient well-being and overall state of health will result in better rehabilitation.

The basic research programs into the causes and consequences of end-stage renal disease served as the underpinning which allowed us to plan and implement the above research at the patient level. This research was carried out at the level of biochemistry, molecular biology, cell biology, tissue culture, and animal experimentation. It is quite important that it be allowed to continue at a high level since the field is advancing rapidly.

DIABETES

Question. About ten percent of adults in the United States have diabetes, and 70 percent of them are overweight. Dr. Gorden, what is the relationship between diabetes and being overweight?

Answer. The form of diabetes that most adults get is called Type II or noninsulin-dependent diabetes (NIDDM). This condition is characterized by a resistance of the body to the action of insulin so that despite the presence of the hormone (frequently at even greater than "normal" levels) the cells of the body perceive a lack of insulin. When this happens to a sufficient degree, then blood sugar rises and diabetes may ensue. As you have noted, a large proportion of people with NIDDM are substantially overweight; although among obese people, a minority have diabetes. Interestingly, one of the major effects of obesity can be to induce insulin resistance. It would appear that individuals with a particular proclivity for developing obesity-related insulin resistance or with other predisposing tendencies (perhaps genetic) toward insulin resistance that become additive with obesity are at especially high risk for diabetes in association with being overweight. The detailed nature of these interactions is not yet

clear and is an active area of research supported by the NIDDK. What is clear is that many patients with NIDDM and obesity display marked improvement in their diabetic condition if they return their weight toward normal levels.

Question. Adult diabetes apparently begins with a decreasing ability of the body to respond to insulin, which forces the pancreas to produce more to get the desired effect. I understand that new research suggests that these subtle metabolic abnormalities can be detected decades before the decrease actually develops. Is that correct?

Answer. Noninsulin-dependent diabetes (NIDDM or Type II diabetes) which usually occurs in adults does appear to be the result of the body's decreased sensitivity to its own insulin in conjunction with an inability to produce enough insulin to overcome this insensitivity. These two characteristics can be measured and the presence of such metabolic defects even in an early subtle stage can be ascertained in people before they become overtly diabetic. However, it is important to note that these testing methods require fairly sophisticated clinical research-based technologies that are not widely applicable to the medical care community at this time. We are hopeful that further research will provide us with accurate and simple tests in the future.

Question. Does early detection help, or is this an irreversible process?

Answer. At this time, we have no way to effectively intervene in the underlying process. However, we do know that there are coincident risk factors that are subject to modification such as obesity and, probably, poor physical fitness. Therefore, if it becomes possible to easily and reliably detect early mild abnormalities that put a patient at great risk for NIDDM in the future, then that patient can be especially encouraged and helped to maintain a healthy body weight and level of physical fitness.

METABOLIC RATES

Question. Doctor Gorden, your Institute put out a press release last February that reported that people who have a slow metabolism rate are at higher risk of gaining weight than those with a fast metabolic rate. This was the result of a four-year study funded by your Institute with the results published in the New England Journal of Medicine on February 25, 1988. Dr. Gorden, what is new about these findings? I thought this was generally known, as I have heard it discussed for at least three decades.

Answer. It is true that we have long suspected that differences in the rates at which people metabolize nutrients may be an important determinant of weight gain. However, while there is considerable anecdotal data on this point, there has been very little scientific evidence.

The study you refer to was the first thorough scientific examination proving that a low metabolic rate predisposes some people to weight gain. This investigation was carried out at the NIDDK's intramural facility at Phoenix, Arizona. Our scientists

there have been studying the local Pima Indian population for many years with respect to the Pima's unfortunate genetic tendency to develop non-insulin dependent diabetes.

Pima Indians also are prone to obesity. In this four-year investigation of weight gain, groups of Pima's were studied using two sophisticated quantitative methods of measuring energy expenditure under very controlled conditions. One method measured resting metabolic rate. The other measured 24-hour energy expenditure using a system, first developed at Phoenix, called a respiratory chamber.

Our scientists found that people who have a slow metabolism were at significantly higher risk for gaining weight than people who have higher metabolic rates, and that family members tended to have similar metabolic rates. We hope that this more precise understanding of individual differences in energy expenditure, and the knowledge that obesity may have a genetic basis, will stimulate the development of new preventive and treatment strategies for this major health problem.

DIGESTIVE DISEASES RESEARCH

Question. Dr. Gorden, last year the House and Senate Appropriations Committees, as well as the Authorizing Committees placed special emphasis on the need for the NIDDK to accelerate research training programs for digestive diseases. Instead you cut digestive diseases training. Can you explain why you did this?

Answer. The NIDDK is acutely aware of the critical need for trained research personnel to advance progress in the area of digestive diseases. In FY 1989 trainee stipends for NIH programs were increased to remain competitive with other career opportunities for young physicians and scientists. Therefore, the NIDDK was required to reduce the number of fellowships and training grants that could be awarded. Consequently, the total number of NIDDK trainees will be reduced from 916 in FY 1988 to 811 in FY 1989. In light of this reduction, it was not possible to accelerate research training programs for digestive diseases.

Question. Dr. Gorden, what are the activities of the Digestive Diseases Advisory Board?

Answer. Since its statutory establishment in 1980, the NIDDK's National Digestive Diseases Advisory Board (NDDAB) has been charged with periodically updating the long-range plan formulated by the National Commission on Digestive Diseases. Last year the Board began a two-year effort to carry out this charge, resulting in several initial recommendations. For example, considerable time was devoted to the subject of clinical trials. Advice was sought from the digestive diseases research community to identify clinical trials that could be initiated at this time, as well as administrative mechanisms to plan and implement future trials. Other issues addressed by the Board include the development of future research manpower in the field of digestive diseases, and third-party reimbursement of enterostomal patient education -- a project that may serve as a model for other digestive diseases.

The Board's plans for the coming year include developing recommendations to enhance the digestive diseases research centers program; seeking information about patient selection criteria for liver transplantation; developing recommendations to increase the number of trained digestive diseases epidemiologists in the United States; continuing to work with the NIDDK in developing a digestive diseases epidemiologic data base; continuing to address nutrition issues within the Board's mandate; recommending additional activities as needed; and reviewing developments in digestive diseases that warrant additional efforts in professional, public, and patient education. In recent years the Board has also organized conferences on the "Impact of Modern Molecular Methods on Studies of Gastrointestinal and Liver Diseases," "The Biology of Cell Membrane Damage and Repair," and "Mechanisms and Management of Hepatobiliary Disease."

Question. Dr. Gorden, can you tell us how the Digestive Disease Centers program is going?

Answer. The Digestive Diseases Centers Program continues to be a key element in our strategy to combat digestive diseases. This strategy is multifaceted and in addition to the Centers Program, includes programs in basic research, research training, and clinical studies. There are 12 digestive diseases core center grants. They have proven to be a major stimulus for the gastroenterology and hepatology programs at the institutions where they are located and provide foci for the world community of biomedical research. These grants support core laboratory facilities and enable pilot studies that serve as an underpinning of the basic research being pursued at these centers. The centers support research in areas including liver diseases and disorders; inflammatory processes of the digestive tract; gastrointestinal function and dysfunction in areas including motility, absorption, and secretion; and fundamental studies of the structure and function relationships in the digestive tract. Diseases addressed by investigators associated with these centers include primary biliary cirrhosis, gallstone disease, ulcerative colitis and Crohn's disease, and diarrheal diseases. The centers enable rapid response to research opportunities by fostering interdisciplinary collaboration and the funds and laboratory resources to conduct exploratory studies. Exploratory and pilot studies, if fruitful, can provide the basis for research grant requests to undertake new directions of basic and clinical studies. The centers will support pilot and feasibility studies intended to test new research leads on a limited basis.

The digestive diseases research centers have proven remarkably productive. They provide opportunity for leadership in the fight against digestive diseases, a means to pursue early research insights, and a high quality of core laboratory resources for existing research programs. The digestive diseases that impact on the Nation are of great magnitude and complexity. Their study is benefiting remarkably from the broadly-based, coordinated efforts provided by the Digestive Diseases Centers Program.

MODIFICATION OF DIET IN RENAL DISEASE (MDRD) STUDY

Question. What is the status of the Modification of Diet in Renal Disease study begun last year, and what do you estimate of the costs of this study?

Answer. This is a legislatively-mandated clinical trial that has just entered its full-scale phase. It will be conducted in 15 clinical centers where 800 patients will be randomized into two groups. The trial is primarily designed to determine whether it is possible to delay or arrest the progression of chronic renal disease to end-stage renal disease with low protein and phosphorus diets. The trial potentially could result in significant cost savings to the Federal government if it delays the need for dialysis and transplantation therapies for end-stage renal disease. The cost of these programs is currently approaching $3 billion annually under the Medicare Program.

The NIDDK will provide $7-9 million annually for the full-scale phase, with total cost to the NIDDK over the life of the trial estimated at $45-50 million. The Health Care Financing Administration is paying the MDRD laboratory and patient care costs through the Medicare Trust Fund.

Question. Since there has not been separate funding appropriated for this study, how have you been covering the costs?

Answer. To buffer the effects of the trial on the Institute, the NIDDK has raised the projected FY 1989 payline for the Division of Kidney, Urologic, and Hematologic Diseases (DKUHD) from the 15th percentile to the 20th percentile by using funds from the Diabetes Division to fund kidney disease of diabetes in the DKUHD. However, the Kidney Division is still projected to fund at a payline about five points lower than each of the other two Divisions.

Question. How many fewer grants have not been or will not be funded as a result of the transfer of funds to cover the cost of the MDRD study?

Answer. The size and cost of the MDRD displaces approximately 30 other regular research grants.

DIABETES CONTROL AND COMPLICATIONS TRIAL

Question. In June of 1988, NIDDKD announced that patient recruitment for part one of the Diabetes Control and Complications Trial (DCCT) had been completed and that additional volunteers were being recruited who had diabetes for less than five years. What difficulties have been faced generally in recruiting volunteers to participate in the DCCT?

Answer. Difficulties in recruiting volunteers for the DCCT were not unexpected. We were seeking a relatively large number of patients who had to completely fulfill a significant number of particular qualities that fit the study requirements. In addition, we were asking these volunteers to commit themselves to a long-term study (at least five years) which would require a significant amount of effort on their parts and for which we could not offer

them any guarantee of immediate personal benefit. We have asked volunteers to altruistically help the medical research community find answers to questions in the hope that they and others might benefit in the future. I am happy to report that since our last discussion the DCCT has closed its recruitment efforts because those volunteers presently in the screening pipeline will meet our goal.

Question. In what ways could recruitment be accomplished more rapidly?

Answer. Now that recruitment is complete we can look back and see that our efforts appeared appropriate and we did quite well in the face of optimistic initial projections. Some of the publicity methods we developed over the course of the effort might have been instituted earlier in the process, but a recruitment effort for such a necessarily complex, selective clinical trial had never before been attempted and we had to learn as we went along.

Question. Given the current pace of recruitment and progress in the DCCT, when can we expect to receive study findings regarding the benefits, if any, of "tight blood glucose control"?

Answer. The study was designed to follow each of our volunteers for at least five years. This would project to a conclusion date in very late 1993 or early 1994. Of course, if our independent monitoring group, which evaluates study progress on a regular basis, finds that the study results are definitive in a shorter period, then we shall stop prior to that date.

Question. Consistent with proper scientific method, are there ways in which the progress of the study can be accelerated?

Answer. The development of the early signs of diabetic complications takes place over several years. In a study like the DCCT where we are attempting to compare different treatments on this process, we are required to wait sufficient time to observe the relative progression of measurable signs. Therefore, we have no way to speed up the natural time course in order to get a quicker answer. Of course, if our initial estimates of the impact of our "experimental" therapy were too modest, then we might see a definitive result sooner than expected. That is one of the reasons we have an independent monitoring group to periodically review the status of the study and tell us whether to continue or conclude our efforts.

Question. Are sufficient funds allocated to the DCCT for the study to progress optimally?

Answer. The NIDDK considers the Diabetes Control and Complications Trial one of its high priority clinical trials and will continue to commit significant resources towards its successful completion. The DCCT will be fully supported at the President's budget level.

DIABETES RESEARCH

Question. Research findings have been reported in recent years that have identified the presence of "genetic markers" in persons who have diabetes. Reports have suggested that such genetic information might be useful in identifying persons susceptible to diabetes, before the disease is manifested, presenting an opportunity for preventive intervention. Please describe the status of research concerning the identification of persons susceptible to Type I and Type II diabetes by such means as "genetic markers."

Answer. Our ability to identify individuals destined to become diabetic prior to the clinical manifestations of diabetes mellitus would indeed be an extremely important accomplishment. It is in this direction that numerous investigators are directing their attention. Since there are two major forms of diabetes which can be differentiated by various clinical and metabolic criteria, it is best to address the status of research concerning genetic markers in diabetes according to these two types: Type I, insulin-dependent diabetes mellitus (IDDM) or Type II, noninsulin-dependent diabetes mellitus (NIDDM).

Type I diabetes appears to be caused by an inappropriate attack by the immune system on the insulin producing cells of the pancreas resulting in a total destruction of the body's capability to provide the hormone. Not surprisingly, it has been known for the past decade that there is an association between certain genes involved in immune system function (HLA genes) and an individual's chances to develop IDDM. Recently, more sophisticated techniques have been utilized to expand our knowledge of this relationship. Researchers have identified a specific DNA sequence within the HLA genes which appears to contribute a more specific marker for IDDM. Unfortunately this marker does not completely explain or account for all of the known inheritable nature of IDDM so the search for better genetic markers or combinations of multiple markers continues as a major research effort.

From clinical and epidemiologic studies it is clear that there is a major genetic component to the underlying cause of NIDDM. Unfortunately, we know little about the basic underlying causes of this form of diabetes to guide our search for the important genes. There have been a number of studies looking at potential marker genes which might be predicted to be important such as the insulin gene, the insulin receptor gene, and the glucose transporter gene. Unfortunately, none of these studies has yet shown that these genes are good markers for NIDDM. However, the recently developed power of modern molecular genetics makes it possible to identify marker genes even if we don't yet know what those genes are doing if we have the appropriate families with a high prevalence of the disease in question. Approximately 50 percent of the Pima Indians in Arizona above the age of 40 have NIDDM. This Native American population has been extensively studied on a metabolic level for more than 20 years by intramural scientists of the NIDDK. At this moment the appropriate genetic marker studies are getting underway which may provide extraordinarily important answers to our genetic questions about NIDDM.

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Question. Please discuss the amount and nature of NIH resources relevant to the prevention of diabetes in susceptible individuals.

Answer. In order to discuss the prevention of diabetes in susceptible individuals it is best to address each of the two major forms of diabetes as separate diseases. Type I diabetes or insulin-dependent diabetes mellitus (IDDM) has been shown to be the result of an immune response gone awry. Therefore, researchers have concentrated their efforts at prevention of IDDM on modifying the susceptible person's immune system. At this time the only clinically applicable tools we have for accomplishing this feat are immunosuppressive and chemotherapy agents that are used routinely against cancer or to prevent organ transplant rejection. Unfortunately, these modalities are extremely toxic and may cause a more life-threatening condition than IDDM. For this reason, the development of more specific and less toxic immune therapies are presently being examined. These new approaches are at stages of study which necessarily precede human trials and are being carried out on several animal models of IDDM.

When attempting to prevent Type II or noninsulin-dependent diabetes (NIDDM), the most promising and active area of research concentrates on obesity control. Obesity is the single most significant risk factor for NIDDM that is potentially modifiable. The NIDDK supports a wide array of research directed at understanding why obesity develops, how it contributes to other conditions like NIDDM and how it can be treated. These investigations include basic laboratory studies on fat cells and the biochemistry of fat metabolism, studies of genetically obese strains of laboratory animals, clinical studies of energy metabolism in humans with and without NIDDM, and intervention studies in populations at high risk for obesity and NIDDM.

Diabetes prevention-related research is supported by the NIDDK through multiple mechanisms including intramural research, regular research grants, centers grants, and contracts. It is difficult to precisely quantitate the extent of our support since so many lines of research across the whole spectrum of our activities and areas of interest are relevant to diabetes prevention efforts. Our expenditures on obesity research exceed 20 million dollars per year, and the immunologic aspects of IDDM add several million more.

Question. How much of this research devoted to diabetes prevention relates to improving the effectiveness of preventive interventions, such as weight reduction counseling?

Answer. A great deal of our prevention-related diabetes research support is directly related to improving our ability to intervene in the disease process. Virtually all of the immunology-related investigations of IDDM are very relevant to efforts at developing clinical interventions. However, at this time, experimental studies are still at pre-clinical stages for most of the newer, most exciting approaches.

Preventive interventions for NIDDM are in many cases being developed and tested directly in diabetic patients. This has been

possible because the interventions under study are in the realm of behavioral changes to minimize obesity and other coincident risk factors. It would not be inappropriate to consider virtually all of the NIDDK-supported obesity research as preventive intervention related, but there are several examples of specific studies which are pertinent to your question. At each of the Diabetes Research and Training Centers (DRTCs), there are model demonstration units (MDUs). At one of the MDUs, the research group is trying to develop life style modification strategies in an inner city, predominantly black population at high risk for NIDDM. Another set of studies supported by a regular research grant from the NIDDK is rigorously testing the efficacy of behavior modification techniques for sustained weight loss in obese patients.

Question. How much of diabetes research is devoted to improving methods of communicating health messages to persons with diabetes, such as educating diabetics on effective blood glucose control?

Answer. Diabetes research devoted to improving methods of communicating health messages to persons with diabetes is primarily performed at each of the six Diabetes Research and Training Centers (DRTCs) funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). These six centers have a total budget of $10,393,000. Approximately 33 percent of this budget is devoted towards training and education research designed to improve patient outcome. The research focus at each center reflects individual expertise and interest. Examples include: the development of model care programs, development of new methods to incorporate research results into patient care, the development of a training program for health professionals to more effectively educate their patients, and investigation of unique behavioral traits in diabetic patients that may affect their care such as risk-taking behaviors in adolescents.

KIDNEY DISEASE

Question. Please discuss the projected development of the Modification of Diet in Renal Disease Study which was announced in December of 1988 and is designed to explore the prevention of kidney disease in diabetics.

Answer. The Modification of Diet in Renal Disease (MDRD) clinical trial is a legislatively-mandated study which will test whether low protein and low phosphorus diets and strict blood pressure control can retard the decline of kidney function that occurs in people with chronic kidney disease. We are collaborating in this study with the Health Care Financing Administration.

This major initiative will examine the prevention and treatment of chronic progressive kidney disease. The study's full-scale phase, which has just begun, will examine patients aged 18 to 70 over the next four years. Eligibility criteria for the study require that participants not be taking insulin; not be pregnant, breast feeding, or planning to become pregnant; not be receiving dialysis treatment; and not be a recipient of a kidney transplant.

It is hoped that the trial will demonstrate the value of diet and/or blood pressure control in delaying the onset of end-stage renal disease (ESRD). This would lead to improved quality of life for kidney patients and to savings to the Federal government, which funds dialysis treatments and kidney transplantation through the ESRD medicare program. The costs of this program now approach $3 billion annually.

DIGESTIVE DISEASE RESEARCH

Question. A possible treatment for the debilitating digestive disease ulcerative colitis was briefly reported in the January 21, 1989 issue of Lancet. It involves replacing the bacteria in the colon of the colitis patient with bacteria from a disease-free donor. Is this a sound approach that would be amenable to further research?

Answer. The report by Dr. Justin D. Bennet and Dr. Mark Brinkman provides an intriguing lead that they and other researchers are likely to pursue. It is based on known concepts and existing hypotheses. The treatment described was attempted on just one person--Dr. Bennet--both an author of this article and the patient treated. The key feature of the treatment described was the substitution of the intestinal flora from a normal person for the flora in the intestine of an ulcerative colitis patient. The hypothesis--that the cause of ulcerative colitis is related to the action of certain intestinal bacteria on common intestinal constituents--is reasonable.

This report by Drs. Bennet and Brinkman does not lead directly to patient treatment. A process of science can be expected that will include further careful assessment of the hypothesis and an evaluation of possible preliminary means to test this and related hypotheses in laboratory models rather than in humans. The potential risk to human patients will have to be understood and evaluated before any human studies are pursued. These risks include introducing new, and potentially worse, pathogens to the patient. Alternatives to unspecified and uncharacterized intestinal inocculum will most likely be considered. If and when human studies are deemed appropriate, initial studies will be conducted on relatively few patients to determine safety of the procedure and the materials used. The final stage of study, if warranted, would be a properly constructed clinical trial.

CYSTIC FIBROSIS CENTERS

Question. The Committee was pleased to see that your Institute reissued a research solicitation for CF centers. What has been the response to this solicitation?

Answer. We have received five applications in response to our research solicitation for cystic fibrosis centers. The applications have been reviewed by a National Institutes of Health study section and the general quality of them is good. Our National Advisory Council will make the final decision on funding at its May meeting, but we anticipate that at least two centers

will be approved. These centers will be in addition to the two centers we already support, at Columbia University's College of Physicians and Surgeons and at Case Western Reserve University.

OSTEOPOROSIS

Question. Doctor, can you talk a little more about the importance of the discovery of estrogen receptors on bone cells?

Answer. The finding you refer to relates to osteoporosis, a serious disease characterized by the loss of bone density. Osteoporosis is most prevalent in older women and increases the fragility of bones, making them more prone to fracture. It is important to recognize that bone is a dynamic living tissue and that the substance of the tissue undergoes constant renewal in order to maintain structural and functional integrity. Until recently, we knew only that estrogen seemed to be important in maintaining bone mass because many post-menopausal women develop osteoporosis, and these women have reduced blood levels of estrogen. Currently, in fact, the administration of replacement estrogen is the most widely accepted treatment for osteoporosis.

Within the past year, however, NIDDK grantees reported that maturing bone cells have receptors for this hormone and that the binding of estrogen to its receptor stimulates the synthesis of various growth factors. These growth factors in turn may regulate the synthesis of a type of collagen, which becomes a major component of the bone matrix. This evidence suggests that estrogen, and more specifically the estrogen-receptor complex, plays a direct role in bone formation and maintenance. A theory has been advanced that estrogen deficiency may cause the bone loss seen in osteoporosis because of an impairment of collagen synthesis -- a short-circuit in the bone renewal process. Much more work needs to be done to better understand how estrogen affects bone, but at this point I think we can say that these findings strengthen the rationale of using estrogen replacement to prevent osteoporosis, and that new therapies for osteoporosis might potentially be developed around this exciting knowledge of the estrogen receptor.

ENDOCRINOLOGY

Question. In your opening statement you have told us about the importance of endocrinology to understanding and curing diseases. Can you give us an example?

Answer. I'm always glad to get the chance to talk a bit about endocrinology, because I think it's one of the most important medical disciplines. The endocrine system and its hormones really affect virtually every process that goes on in the body. For that reason, endocrinologists are often helpful in providing treatments for diseases that are not directly caused by hormone malfunction. An example I discussed earlier is the diagnosis and management of thyroid cancer. Thyroid hormones are used both to locate tumors and in suppression of tumor cell growth. Further, hormone therapies have proven to be very important in the treatment of breast and prostate cancer. Another example is the discovery of estrogen receptors on bone cells. This is an area under active

investigation right now, and may lead to new treatments for osteoporosis. Endocrinology also plays a role in immunologic disorders, neurologic diseases, cardiovascular disease, and psychiatric disorders. We recently issued a request for applications for "Programs of Excellence in Endocrinology" to encourage additional clinical and basic research in this area.

STRUCTURAL BIOLOGY

Question. Structural biology is a topic we keep hearing about. Is your Institute active in this area?

Answer. Yes, the NIDDK is very much involved in the application of two powerful techniques for studying molecular structure, particularly in relation to the development of new therapies for acquired immunodeficiency syndrome. NIDDK intramural scientists pioneered the use of nuclear magnetic resonance spectroscopy (NMR) to study the structure of biologically important molecules. Now these scientists are using this technology to define the structure of human immunodeficiency virus (HIV) proteins. In addition, the NIDDK has a senior group of intramural investigators with considerable expertise in X-ray crystallography. This technique made possible the discovery of how antibody and antigen molecules are held together, and has led to the development of more specific drugs, including agents to combat hypertension. In complementary studies to NMR, NIDDK scientists are using X-ray crystallography to investigate the structure of HIV proteins, with an eye toward developing new anti-HIV drugs. In fact, you may be interested to know that recently Merck and Company announced they have solved the structure of an HIV protease. I'm pleased to tell you that the lead investigator of this study, Dr. Manuel Navia, was a former post-doctoral fellow of Dr. David Davies in the NIDDK intramural program.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

INTERSTITIAL CYSTITIS

Question. Dr. Gorden, I understand the NIDDK has prepared a 5-year plan for Interstitial Cystitis (IC) research. What is the status of that plan? Does the NIDDK support the establishment of a national registry of self-identified or physician-identified IC patients? Why or why not?

Answer. The NIDDK has prepared the five-year plan and transmitted it through the Department to the Senate Appropriations Committee. The plan states that the NIDDK does not support the establishment of a national registry of self-identified or physician-identified IC patients. The reason for this, as stated in the five-year plan, is that the Institute believes that a pilot IC Data Base would contribute more to furthering research on IC than would a national registry of individuals whose clinical features can be expected to be extremely variable. Essential to the concept of a pilot IC Data Base is that it would include data that had been uniformly collected based upon clinical determinations of physician scientists who are using the same set of objective, measurable, and verifiable parameters.

Question. Has the NIDDK established diagnostic criteria for IC? If so, has the NIDDK considered using the diagnostic criteria as a screening method for an IC National Registry or Data Bank that would include patients from across the country as well as include their epidemiological information?

Answer. In this regard, I am pleased to report that a preliminary set of diagnostic criteria to be used for research purposes was agreed upon at a November 1988 IC workshop sponsored by the NIDDK. We believe the next step is to use these criteria in conducting biomedical research studies and in establishing the pilot IC Data Base described in the five-year plan. We think it would be premature, at this time, to attempt to use these criteria as a screening method to establish an IC National Registry or Data Bank that would include epidemiologic information.

KIDNEY DISEASE OF DIABETES MELLITUS

Question. Dr. Gorden, how many approved research grants was the NIDDK able to fund last year in the area of diabetes-related kidney disease? As you know, the American Diabetes Association, the Juvenile Diabetes Foundation International, and the National Kidney Foundation are requesting that Congress appropriate an additional $5 million for this research in FY 1990. How would the NIDDK use an additional $5 million if Congress increased the NIDDK appropriation by $5 million above the President's request?

Answer. In 1988, we supported 48 projects including research grants, contracts and intramural research studies for a total of nearly $9.4 million. The initiative on the Kidney Disease of Diabetes Mellitus would be implemented primarily through the investigator initiated research grant mechanism. An additional $5 million would support between twenty and twenty-five grant awards.

CURRENT SERVICES BUDGET LEVEL

Question. Dr. Gorden, the Coalition of Voluntary and Professional Organizations in Support of the NIDDK informs me that the President's FY 1990 budget request for the NIDDK will not fully fund ongoing research projects and centers. How much would you need to maintain at least current services?

Answer. Our Current Services estimate for 1990 was $630.0 million which is about $52.8 million greater than the Budget Request.

Question. How would any additional dollars be spent beyond current services?

Answer. Our first priority would be to decrease the negotiated reductions on our research grants and to increase the number of new and competing renewal awards. Second, we would decrease the negotiated reductions on research centers. After these two highest priorities are met, we would like to support some of the backlog of clinical trials.

MODIFICATION OF DIET IN RENAL DISEASE

Question. Dr. Gorden, what is the status of the Modification of Diet in Renal Disease (MDRD) study begun last year, and what do you estimate the costs of this study to be? Since I understand there has not been separate funding appropriated for this study, how have you been covering the costs? How many fewer grants have not been or will not be funded as a result of the transfer of funds to cover the cost of the MDRD study?

Answer. The major legislatively-mandated clinical trial on Modification of Diet in Renal Disease (MDRD) entered the full-scale phase in September 1988 and will involve an estimated 800 patients. Fifteen clinical centers are participating in this trial, the clinical part of which is expected to conclude at the end of 1992, to be followed by a year of data analysis and reporting. The primary purpose of this trial is to determine whether low protein and low phosphorus diets can delay the onset of end-stage renal disease, which costs the nation nearly $3 billion annually under Medicare to treat via dialysis and transplantation. This study is a collaborative effort between the NIDDK and the Health Care Financing Administration (HCFA), which administers the Medicare program. Total costs of the study to NIDDK are estimated at $45-50 million.

In the absence of appropriated funds for this study, its costs have been borne by the Kidney Division of the Institute. As a result of the fiscal impact of the MDRD, this Division was facing the prospect of an FY 1989 payline of the 15th percentile earlier this year. As the year progressed, however, the NIDDK had an opportunity to buffer the effect of the MDRD on the Kidney Division by identifying and funding diabetes-related grants in that Division. As a result, we now project that the Kidney Division will fund to the 20th percentile in FY 1989 rather than the 15th percentile. The Kidney Division is still projected to fund at a payline about five points lower than each of the other two Divisions, however.

To answer your very last point, let me note that the annual average cost of the full-scale MDRD is about $9 million. For FY 1989, the first year of the full-scale study, the cost is about $7 million. If this $7 million were not required to fund the MDRD in FY 1989, we would be able to fund 30 additional investigator-initiated research project grants.

NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. DUANE ALEXANDER, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next we will go to the National Institute of Child Health and Human Development, Dr. Duane Alexander.

Dr. ALEXANDER. The National Institute of Child Health and Human Development supports and conducts research on biomedical and behavioral issues throughout the life cycle. This includes research on birth defects, mental retardation, pediatric, and maternal AIDS, Sudden Infant Death Syndrome, problems in physical and behavioral growth, learning disabilities, and prevention of childhood illness and injuries. In addition, issues concerning origins of lifestyle patterns that influence adult health are studied as are issues concerning fertility regulation, infertility, and reproductive health.

Because our mandate is so broad, our research affects each individual in the country and deals with problems that exact a huge economic and emotional toll.

IMMUNOCONTRACEPTIVE VACCINE

One of the most important advances in the past year is an accomplishment by one of our grantees who succeeded in achieving 100 percent effective contraception in animals, both male and female, using an immunocontraceptive vaccine he developed. This important advance in family planning also has application to the problem of infant mortality. Infant mortality is linked with low birth weight, and babies born as a product of an unplanned pregnancy are more likely to be low birth weight.

BIRTH DEFECTS

Birth defects remain the No. 1 cause of infant mortality. We support a comprehensive research program to identify and map those genes responsible for early development where errors result in birth defects. We are participating in the NIH human genome mapping effort, and have established a gene probe repository that has become a valuable international resource for genetic research.

We have a leading role at NIH in the area of developing animal models to study specific genetic disorders. We are close to the time when this basic research will translate into clinical advances.

SUDDEN INFANT DEATH SYNDROME [SIDS]

The Institute recently convened a panel of experts to develop a 5-year research program on SIDS similar in scope to the 5-year re-

search plan we embarked upon to combat the problem of childhood injuries and their prevention.

VACCINE CLINICAL TRIALS

Progress continues in the clinical trials of the vaccines against typhoid fever, pertussis, and *Hemophilus influenzae* meningitis developed in our intramural laboratories. Based on the successful field trial in Nepal, the typhoid vaccine is being marketed. Results from partially completed phase II trials of the pertussis and *H. influenzae* vaccine are extremely encouraging, and phase III field trials are being planned.

PEDIATRIC AIDS

Pediatric AIDS has become a leading cause of death among children and adolescents, and the NICHD has launched an intensive broad-based research program to study how the AIDS virus is transmitted from mother to child, the effect of the virus on pregnancy and fetal and child development, methods to prevent the onset and progression of disease in HIV positive children, treating children who are ill with AIDS, and methods to prevent transmission of the AIDS virus.

NICHD SPAN OF RESEARCH

As outlined in my prepared statement, the NICHD supports a wide array of research ranging from studies of basic molecular biology to the effects of day care on child development. This research spans the scientific spectrum and the life cycle spectrum as well.

PREPARED STATEMENT

Our fiscal 1990 budget request is $417,064,000. I will be pleased to answer any questions.

[The statement follows:]

STATEMENT OF DR. DUANE ALEXANDER

During the life cycle of the developing human, each phase of development is uniquely vulnerable to problems that can threaten health and well-being. The National Institute of Child Health and Human Development (NICHD) responds to this challenge by supporting and conducting research on biomedical and behavioral issues related to each phase of the life cycle.

The fetal period is perhaps the most hazardous since problems arising during this time can result in death or lifelong disability. Birth defects are a leading cause of infant mortality, and other conditions such as mental retardation or inborn errors of metabolism have their origins in this period. Sudden Infant Death Syndrome strikes during early infancy, and problems in physical and behavioral growth, learning disabilities, and injuries due to accidents affect millions of children and adolescents. In addition, nutrition and lifestyle patterns that influence adult health begin to form. The teen and early adult years are times of emerging sexuality and issues concerning fertility control, infertility, and reproductive health are paramount. Some problems transcend all age groups: infections as a source of acquired mental retardation and, more recently, AIDS, are serious problems that strike without regard to age or life cycle phase.

The NICHD conducts and supports research designed to prevent or alleviate these and many other problems. Because its mandate is so broad, the research mission of the NICHD affects virtually each individual in the U.S. and deals with problems that exact a huge economic and emotional toll.

Although the scope of these problems may seem overwhelming, progress is being made against many of them.

One of the most important advances of the past year is an accomplishment by an NICHD grantee who succeeded in achieving 100 percent effective contraception in animals, both male and female, using an immunocontraceptive vaccine he developed. This vaccine, based on inducing antibodies to a protein specific to sperm, utilizes the host animal's own immune system to prevent pregnancy. We hope this vaccine will be an early step toward developing a comparable vaccine for humans. Immunocontraceptive vaccines for humans are an exciting prospect because such vaccines are likely to be safe, effective, inexpensive, reversible, convenient, and acceptable to a wide range of people. This work is a direct result of the NICHD Contraceptive Development Initiative presented to Congress in 1986. Although immunocontraception is an exciting prospect, the NICHD continues to support work to develop other new forms of contraception and to improve those already on the market.

A breakthrough in developing an entirely new approach to contraception is important not only from a family planning standpoint, but also to the problem of infant mortality. Infant mortality is inexorably linked to low birth weight and babies born as a product of an unplanned pregnancy are much more likely to be low birth weight than are "wanted" babies. For example, a significant proportion of teen pregnancies, most of which are unplanned, result in a low birth weight infant. "Wantedness" thus becomes another of the life style factors such as smoking, drug and

alcohol use, poor nutrition, and close spacing of pregnancies that are linked with low birth weight.

The rate of decline of this nation's unacceptably high infant mortality rate has slowed in the past few years despite advances in medical technology, many supported by the NICHD, which have resulted in improved survival rates for premature and low birth weight infants. The infant mortality rate is closely tied to the rate of low birth weight, and this rate has stayed nearly constant at 7 percent for many years now. It is becoming apparent that part of the incidence of low birth weight and thus infant mortality is closely linked to factors that are not easily amenable to change such as intergenerational and genetic effects and certain life style factors.

Birth defects remain the number one cause of infant mortality. Many genetic disorders such as osteogenesis imperfecta, often called brittle bone disease, or neural tube defects are in themselves rare diseases, but they are representative of the many disorders that result from faulty development. The NICHD approach is to support a comprehensive research program grounded in the basic sciences, exploring embryo development and the identification and mapping of those genes responsible for early development, along with new treatments for some disorders. The NICHD is participating in the NIH human genome mapping effort, and has established a gene probe repository that has become a valuable international resource for furthering genetic research. The NICHD has a leading role at NIH in the area of transgenic technology, that is opening new doors for the development of animal models to study specific genetic disorders. We are close to the time when this basic research will translate into clinical advances.

Not all conditions threatening the lives of newborns are yielding to research. One of these persistent problems is SIDS, the leading cause of death in American children between the ages of 1 and 12 months, claiming about 7,000 lives annually. Many hypotheses have been advanced to explain SIDS but the exact causes of this syndrome remain elusive. As a result of a large NICHD study, the epidemiology of SIDS is now well understood but the biological processes involved in it are not.

The critical need for continued research into SIDS, recognized by Congress, has resulted in the development by NICHD of a 5-year SIDS research plan. A committee of experts from various fields related to SIDS has assisted the Institute in preparing a summary of current research findings and areas in need of further study. A common theme runs through the report: an abnormality of development makes some infants vulnerable to internal or external stresses that trigger death. The report enumerates a research agenda to expand our knowledge about these vulnerabilities and the cascade of events that lead to death.

While we have been grappling with the problems of SIDS and infant mortality for a long time now, new problems continue to emerge. AIDS has become the sixth leading cause of death in those from 15 to 20 years of age, the ninth leading cause of death among children 1 to 4 years, and is expected to become the leading cause of acquired mental retardation.

NICHD AIDS-related research is investigating the extent of the AIDS epidemic in women, infants, children, and adolescents; the transmission of the AIDS virus from mother to child; the effect of the virus on fetal and child development; methods to prevent the onset and progression of disease in HIV- infected children; AIDS treatment; approaches to understand and modify the behaviors and attitudes that contribute to the spread of AIDS; and methods to prevent the sexual transmission of the AIDS virus. These studies range from epidemiological surveys to clinical trials and basic research.

Pediatric AIDS is known to affect the central nervous system and clinicians have reported HIV-related CNS symptoms as early as the first few months of life. An NICHD intramural scientist has discovered a possible clue as to why children and adults with AIDS often suffer mental decline or dementia. He has demonstrated that a protein component of the AIDS virus has the ability to starve neurons of substances essential for survival. Understanding the mechanisms by which HIV causes neurological impairment may be the first step to developing a strategy to block its neurological effects.

The NICHD has started a major clinical trial to study the effectiveness of intravenous gamma globulin in the treatment of children ill with HIV infection. Children infected with HIV frequently experience severe, life-threatening bacterial infections. This study is testing the hypothesis that intravenous gamma globulin will significantly reduce the rate of these opportunistic infections, slow the progression of the disease, or prevent other problems associated with the disease. More than 225 children have enrolled in this study, making it the largest clinical trial involving HIV-infected children in the world.

A significant portion of the NICHD AIDS research program is focused on prevention. Studies range from the role that condoms and spermicides play in preventing the transmission of the AIDS virus, to a project with the American Academy of Pediatrics to develop age-appropriate educational materials about AIDS, to programs targeted to Black and Hispanic children and adolescents to develop intervention strategies and techniques to reduce the incidence of high-risk behaviors associated with the transmission of the HIV infection.

While a vaccine for AIDS is probably many years away, Institute scientists are making progress toward developing vaccines for other infections. Perhaps of greatest significance, NICHD intramural scientists have developed and are now testing a new vaccine for Hemophilus influenzae infections in children. Currently, this infection is the leading cause of acquired mental retardation in the U.S. An earlier vaccine developed by this same research group is effective in children above the age of 2 years but the peak incidence of H. influenzae meningitis is 5 months, and there has been no effective vaccine for this age group. A pilot study in Sweden, involving infants 3 to 5 months old, was recently completed. The NICHD vaccine was found to be effective and elicited no serious side effects. Plans are now under way to test the vaccine on a larger scale in infants.

While this vaccine may help cut the occurrence of acquired mental retardation, many more cases of mental retardation are a legacy of one's genes. The NICHD supports a broad research program in the area of mental retardation. Much of the emphasis is on Down syndrome, the most common genetic birth defect associated with mental retardation. Scientists in NICHD Mental Retardation Research Centers and elsewhere are using the latest technology to map genes on chromosome 21, the chromosome responsible for Down syndrome. Investigators in other Mental Retardation Research Centers are studying the behavioral and language development of children with Down syndrome to develop intervention techniques to improve the integration of these children into school and community activities.

Some children, although not retarded, have difficulty learning. It is estimated that as many as 15 percent of school-age children are affected by some type of learning disability. NICHD's leadership in this field will continue with the establishment of several multidisciplinary centers for the study of learning disabilities.

A child's life lost to accidental death is a tragic waste, yet childhood injuries are the major cause of death in children after the first year of life. The NICHD is implementing a 5-year research plan that includes projects designed to identify factors in the home, in school, and in play settings and interpersonal relationships that make accidents more likely to happen. Hopefully, this research will lead to practical applications for reducing the frequency and severity of childhood accidents.

Changes in the American lifestyle, particularly the large numbers of women now in the work force, have raised some new issues that the NICHD has added to its research portfolio. For example, concern has arisen that pregnant women who use video display terminals more than 20 hours a week may be at increased risk for miscarriage. The NICHD plans a comprehensive study of early fetal loss to assess the possible effects of VDT use as well as the effect of other factors such as physical and psychological stress, alcohol use and smoking, and use of certain medications early in pregnancy.

Infant day care is another new focus of research by the NICHD. Since more than half of the infants in the U.S. have mothers who are employed outside the home, it is essential to determine whether care given by someone other than the mother has an untoward effect on child development. A collaborative study of this issue has been initiated by the Institute.

Another consequence of the increased number of women in the work force has been a trend toward delayed childbearing, with a subsequent rise in infertility and other reproductive problems. The NICHD plans to establish a network of reproductive medicine units to study such problems as infertility, endometriosis, premenstrual syndrome, and other disorders affecting sexual health and fertility.

As I have outlined, the NICHD supports a wide-ranging array of research, encompassing studies of basic molecular biology as well as the effects of day care. Not only does this research span the scientific spectrum, it spans the life cycle spectrum as well, affecting infants, children, adolescents and young adults, into the middle years and the beginning of a new generation.

Mr. Chairman, the FY 1990 budget request for this Institute is $417,064,000. I will be pleased to answer any questions you have.

STUDY OF SEXUAL BEHAVIOR

Senator HARKIN. Dr. Alexander, it is my understanding that you have funded in fiscal year 1989 a pilot study for a major national study of sexual behavior which would cost a total of $15 million, $7.5 million of which would be needed in fiscal year 1990. What do we expect to learn by such an expensive national survey about sexual behavior which would be different from what is already known on the subject? Is this specifically targeted for something?

Dr. ALEXANDER. The survey is designed to gain information primarily to help us respond appropriately to the AIDS epidemic. In this fiscal year, we hope to pilot a study which will have a total cost of about $2 million and will study about 2,300 respondents. The information that we gain from this pilot study would then be used to design a larger study of approximately 20,000 respondents.

Every organization and group that has looked at the AIDS epidemic and tried to frame an appropriate response to it has pointed out that we lack basic information on sexual behaviors in this country and recommended that the Government obtain it. What we know is based on data poorly collected about 40 years ago. In order to project estimates of spread of HIV infection as well as to direct our efforts for containing its spread in terms of public education, and targeting those efforts, we need much better and up to date information.

What we hope to gain from this survey is that kind of information.

Senator HARKIN. How long a survey will it be?

Dr. ALEXANDER. The pilot study should be completed within 6 months of the time that we start, including time for analysis of the initial data. That will allow us to then do the planning for the larger scale study. The larger scale study would be conducted in fiscal 1990. It would take approximately 6 months to get that study implemented and another 6 months to actually do the survey work and the data collection.

HEMOPHILUS INFLUENZAE VACCINE

Senator HARKIN. You have some vaccines that you are developing. One is for *Hemophilus influenzae*?

Dr. ALEXANDER. That is correct.

Senator HARKIN. *Hemophilus influenzae,* does that cause meningitis or is that what meningitis is?

Dr. ALEXANDER. One of the diseases that it causes is meningitis. It also causes upper respiratory infections, ear infections, and septicemia, a general infection throughout the body. Meningitis and septicemia are the most dangerous diseases it causes. As Dr. Fauci pointed out earlier, *Hemophilus influenzae* meningitis is the leading cause of acquired mental retardation in the United States, and is one of the leading causes of acquired deafness.

Senator HARKIN. Deafness, that is what happened to my brother. That is what he had. What is the status of this now? It still is one of the leading causes of deafness, meningitis?

Dr. ALEXANDER. Yes; it is. The present status is that we have a vaccine that works in children 18 months and older, but children younger than that do not form adequate antibody levels to protect

them against the disease with the regular vaccine. Scientists in our intramural laboratories and others have developed what is called a conjugate vaccine where we link the particular antigen of *Hemophilus influenzae* to another antigen. In our case it is tetanus toxoid. By that process we sort of trick the body's immune system into making antibodies to the *Hemophilus influenzae* antigen even at a younger age, in infancy.

The pilot studies that we have done indicate that by beginning immunization at 2 months of age and repeating it at 4 and 6 months, we get protective levels of antibody that should effectively eliminate this disease if we can get wide spread immunization of the population. It could be given at the same time as the DPT immunizations that children get routinely in their pediatricians' offices or clinics since the *Hemophilus influenzae* vaccine is bound to the tetanus antigen anyway. We think that we will be able to control this disease.

Senator HARKIN. Great. Let me just finish up on that. This vaccine, is it approved now?

Dr. ALEXANDER. No; we are still in early stages of its development.

Senator HARKIN. What are we looking at?

Dr. ALEXANDER. We are looking at phase II clinical trials at the present time. Next, we will need a phase III clinical trial, a large population study in which we demonstrate the effectiveness and the safety of the vaccine.

Senator HARKIN. How many years of phases II and III?

Dr. ALEXANDER. The phase II study should go another year. The phase III study will take 2 to 3 years to complete.

Senator HARKIN. Do you have enough money in your budget to do this?

Dr. ALEXANDER. There is no money in the budget to conduct the phase III clinical trial that is projected for fiscal 1990.

Senator HARKIN. You can start phase III in 1990?

Dr. ALEXANDER. Yes.

Senator HARKIN. But you have no money for it?

Dr. ALEXANDER. That is correct.

Senator HARKIN. How much money do you need?

Dr. ALEXANDER. The phase III study of the pertussis vaccine that we are working on and of the *Hemophilus influenzae* vaccine will cost about $4 million above what is in the President's budget.

Senator HARKIN. That is for both?

Dr. ALEXANDER. Yes; that is the fiscal 1990 cost for both. There will be costs in 1991 and 1992 as well, but the starting costs that are needed for 1990 are $4 million.

Senator HARKIN. About $444 million including AIDS?

Dr. ALEXANDER. Yes; including AIDS.

Senator HARKIN. And in all of that you are telling me you cannot find the $4 million, or is this just such a low priority?

Dr. ALEXANDER. No; it is a very high priority and we have already put some other things aside in order to proceed with the phase II trials of these vaccines. These are unusual efforts for our Institute. We are not usually in the business of vaccine development. They are being done by us because they came from our intramural laboratories, from Dr. John Robbins, who is one of the

leading immunologists and vaccine developers in the world. So they are not activities that are usually encompassed within our budget.

SUDDEN INFANT DEATH SYNDROME

Senator HARKIN. Last year the committee added $5 million for an expanded effort focused on trials of infants in relation to Sudden Infant Death Syndrome. We asked for a 5-year research plan on Sudden Infant Death Syndrome. What is the status of the research efforts and how about your 5-year plan, what is the budgetary impact of the 5-year plan?

Dr. ALEXANDER. The 5-year plan has been developed with the assistance of the scientific community and has been submitted to the committee. It calls for a broad based effort over the next 5 years involving many disciplines and many approaches to SIDS. It is an optimistic report. The scientists that participated in its development felt that we could make a major impact on this leading killer of infants between 1 and 12 months of age with this kind of an effort.

The $5 million will be spent this year on SIDS. We have two applications pending at the present time for clinical trials of apnea monitors for infants. Each of those has a price tag for the first year of about $3 million. We do not know precisely how much yet because they are both still in the review system.

The remainder of the money is being spent on other grants in SIDS and for research specifically targeted on prevention of low birth weight which is a leading predictor of Sudden Infant Death Syndrome.

FETAL RESEARCH

Senator HARKIN. Let me ask you a question about fetal research. This always comes up in debates. I understand that any research that involves the fetus which is not intended to be of particular benefit to that particular fetus can only be done under guidelines issued by the Department. These guidelines essentially indicate that the research can impose only a minimal risk to the fetus, and any treatment or technique that would be considered more than minimal risk would need to be approved by the Medical Ethics Board.

I understand further that essentially any new technique or new process not previously performed is considered to be more than a minimal risk, and that your institute has had an application on hand for several years that would relate to early diagnosis of fetus with regard to certain disease. However, I understand that the Medical Ethics Board has not been in existence since 1980.

Tell us about the application you have had on hand for several years and what difficulties you are experiencing because of the Medical Ethics Board being inoperative.

Dr. ALEXANDER. All of the statements you made are correct, Senator. There has not been an Ethics Advisory Board since 1980. The application in question is an application from a Dr. Mitchell Golbus at the University of California, San Francisco, that involves performing fetoscopy to obtain a sample of fetal blood or fetal skin

for diagnosis of disorders that cannot be presently diagnosed by amniocentesis or by chorion villus sampling.

Because fetoscopy carries an unknown risk, although that risk is felt to be very small and perfectly acceptable for a fetus that was to go to term, it was felt that the proposal needed to be reviewed by an Ethics Advisory Board because we could not certify that it was minimal risk. That application has been forwarded and has been waiting since 1982. We still carry it on our rolls, but we have not had the Ethics Advisory Board that is required to review such applications in order to permit its funding.

The Ethics Advisory Board existed from 1978 until 1980. During that time it reviewed one application for fetal research that could not be considered minimal risk. It recommended to the Secretary that waiver of the regulations be issued so that that research could proceed. The Secretary at that time agreed with the recommendations of the Ethics Advisory Board, and that research was allowed to proceed and was conducted.

Senator HARKIN. Since then no new procedures have been approved?

Dr. ALEXANDER. No new research supported by the Federal Government that involved more than minimal risk, or uncertain risk to the fetus, not for the benefit of that particular fetus, has been supportable since 1980.

Senator HARKIN. What you are saying is if it is a process not previously performed?

Dr. ALEXANDER. That is correct.

Senator HARKIN. Nothing new has been done since 1982?

Dr. ALEXANDER. That is correct, nothing that falls into that category.

Senator HARKIN. How many of those have come up since 1982?

Dr. ALEXANDER. Most investigators planning to do research that would fall into this category have gone on their own rather than applying for Federal support because they know the door is shut. Procedures such as taking a sample of fetal blood from the umbilical cord, for example, have been developed largely in the private sector until researchers got to the point of knowing the risk associated with the procedure. They needed to know this risk is low before they could apply to us to support research to use those techniques in fetal diagnosis and therapy.

In another example, all the fetal surgery that has been done has been developed in the private sector with support from funds other than from the Federal Government.

LEARNING DISABILITY CENTERS

Senator HARKIN. Last year the committee asked the Institute to establish learning disability centers. What progress have you made in this area?

Dr. ALEXANDER. We have, jointly with the National Institute of Neurological Disorders and Stroke, issued a request for applications for learning disability research centers. An initial triage of those applications has been completed, and the centers that succeeded in that process are now preparing and submitting revised applications, taking into consideration the criticisms that were per-

ceived in the initial review. These revised applications will be received in June and reviewed this summer, and come to our September council for consideration for funding. We still expect and plan to fund two centers as the Congress requested.

CONTRACEPTIVE DEVELOPMENT INITIATIVE

Senator HARKIN. Last, in your opening statement you mentioned an immunocontraceptive vaccine that has resulted from your contraceptive development initiative. Is this initiative complete, and what can you tell us about this? What products or methods are closest to being ready for general use?

Dr. ALEXANDER. The contraceptive development initiative is not complete. It is still in its early stages. It involves application of a number of techniques, immunocontraception being just one of those. This vaccine represents an ingenious concept where antibodies are raised to protein found only on the head of the sperm. By immunizing the female to this particular protein, we block the linking of the sperm to the egg, we block fertilization.

This is in contrast to some of the other immunocontraceptive vaccine approaches that have been tried in other countries which act after fertilization. This one acts before fertilization, so it avoids some of the ethical concerns that would be raised by a post-fertilization method.

Senator HARKIN. Are you developing any new methods of male contraception that would enable men to share more of the responsibility?

Dr. ALEXANDER. Yes; we are. In the animal model the immunocontraceptive vaccine was effective in males as well as females. Other methods for males that we are testing are based on the development of a new long-acting injection of testosterone, and on the LHRH analogues which block spermatogenesis.

Senator HARKIN. That is all I have. Do you have any questions?

VACCINE DEVELOPMENT

Senator BUMPERS. Doctor, the other day we had CDC up here and I forget what they were asking, but they were not asking for anything for hepatitis B vaccines. Is any additional research being conducted on hepatitis B vaccines?

Dr. ALEXANDER. Hepatitis B vaccine work is being supported by the National Institute of Allergy and Infectious Diseases rather than by us. We are working with just the three vaccines, typhoid fever, *Hemophilus influenzae* and pertussis, because these have come from our intramural laboratory of developmental and molecular immunity.

Senator BUMPERS. How are we doing on pertussis?

Dr. ALEXANDER. We have a new pertussis vaccine that is based on inducing antibodies to the pertussis toxoid. We have developed new ways of growing the organism and are isolating the pertussis toxin and toxoiding it with hydrogen peroxide in a way that is irreversible so that the toxoid remains a toxoid instead of reverting to a toxin.

We believe the toxin present in the current pertussis vaccine is the factor that is responsible for the occasional adverse side effects

we see with this vaccine. In studies that have been done in adults and older children and now some preliminary studies in infants, we have used this vaccine and demonstrated highly protective levels of antibody formation without any adverse side effects.

So we think this is a highly promising vaccine; it is probably the vaccine of the future for pertussis. In addition to protecting against disease, it should go a long way to ward eliminating the product liability problem that we are seeing as well as decreasing the number of claims that are made under the National Childhood Vaccine Compensation Act.

Senator BUMPERS. Do you have any kind of a prognostication on the availability of this?

Dr. ALEXANDER. The pertussis vaccine is on approximately the same time schedule as the *Hemophilus influenzae* conjugate vaccine. We are planning phase III clinical trials. They are going to require probably 3 to 4 years from now for completion.

Senator BUMPERS. Before you would apply to FDA for a license?

Dr. ALEXANDER. Yes, sir.

Senator BUMPERS. We are further ahead than I thought. If this continues to be this promising—is it your feeling that it will ultimately wind up being licensed? Do you feel that confident about it at this stage or not?

Dr. ALEXANDER. Only the phase III trials will tell for sure, but based on the phase II studies that are available to date, the vaccine looks so good that I think that both of these will be the vaccines of the future to prevent pertussis and *H. influenzae.*

Senator BUMPERS. Dr. Alexander, that is one of the best pieces of news I have had since this hearing started this morning. I am really encouraged by that, because you know the cost of these vaccines is just staggering.

AIDS

The other question I want to ask you about AIDS, is it absolutely automatic that the fetus will be born with HIV positive if the mother has it?

Dr. ALEXANDER. That is a question we are still trying to answer, Senator Bumpers. It is complicated by the fact that what we detect when the infant is born are basically maternal antibodies. We cannot determine whether the fetus is actually infected at the time it is born, because there is no definitive diagnostic test to differentiate passive maternal antibodies from HIV infection in the infant.

The best estimate at the present time is that approximately 40 percent of the infants born to an HIV-positive mother are infected by the virus.

FUNDING FOR VACCINE CLINICAL TRIALS

Senator BUMPERS. Staff just handed me a note that is mildly disturbing. Are you ready for third stage clinical trials on the pertussis and *H. influenzae* vaccines?

Dr. ALEXANDER. We have them in the planning stages and are on track to have the initial funding for phase III studies in fiscal 1990. As I indicated to Senator Harkin, we do not at the present time have the $4 million that is needed for these two phase III trials.

Senator BUMPERS. Do you need that for 1990 to go to third stage?

Dr. ALEXANDER. Yes; we do.

Senator BUMPERS. I promise you, you have got it. Thank you, Mr. Chairman. Even if I have to write a personal check for it.

Senator HARKIN. Are you going to get together with Mr. Sasser?

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator BUMPERS. If I cannot get that $4 million for that, if it is really that critical—and I wish you would send me a little letter on this and I promise I will not show it to OMB or anything—if you send me a little letter on that, if I cannot get that $4 million, then we are going to fire the Chairman of this committee. [Laughter.]

We will have some additional questions which we will submit for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

VACCINE DEVELOPMENT

Question. I understand you have three new vaccines in the final phases of testing; one for typhoid, one for pertussis, and one for the H-influenza (the leading cause of acquired mental retardation). I understand that the current vaccine for pertussis in one out of every 250,000 cases results in a permanent neurological disability, where the new vaccine is expected to pose no risk. How soon can we get this new pertussis vaccine in place?

Answer. The new pertussis toxoid vaccine developed in NICHD's intramural laboratories is presently being evaluated in Phase II clinical trials. Phase III trials are being planned for initiation in Sweden and the United States in FY 1990. It will take 3 years for those trials to collect sufficient data--numbers of patients and length of follow-up--on safety and efficacy for submission of a license application to the FDA.

EARLY INTERVENTION

Question. As you know, the Washington Post had a very good series on the development of human life which described the almost day by day cell differentiation that occurs in the development of a human life. The story discussed problems that can occur in this process which eventually will lead to disabilities of one kind or another when the child is born and begins to mature. Where are we on research and the capability to intervene, test, and diagnoses at the fetal development stage to correct developmental problems before the infant is born?

Answer. Research advances using the modern tools of molecular genetics and biochemistry have improved our ability to test for, and diagnose certain problems of human development. Progress has been made in identifying specific genes that, when defective, cause certain developmental abnormalities. In addition, DNA sequences that are physically connected to genes thought to cause developmental defects have been identified. These "linked" genes can serve as accurate predictors of potential developmental problems. We can already produce a "DNA fingerprint" of the developing fetus from extremely small amounts of fetal tissue. As additional genes known to cause developmental defects are identified, the more thorough the fingerprint, and the more accurate our prediction can be for developmental abnormalities. Knowing family histories and selecting appropriate DNA "probes" will enable us to successfully predict if a developing fetus will present a certain developmental disorder. No human intervention studies have been attempted or are planned. However, research using animal models has demonstrated that it is possible to "correct" an inherited defect by either genetic or cellular manipulations. This suggests that similar types of intervention could be performed during human fetal development.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question. Last year the Committee added $5 million for an expanded effort focused on trials of monitoring of infants in relation to Sudden Infant Death Syndrome. We also asked for a five year research plan on SIDS. What is the status of research efforts to monitor the occurrence of SIDS?

Answer. There are two major difficulties in developing interventions which prevent deaths from SIDS: (1) we cannot reliably identify an infant that will die of SIDS, and (2) we do not know what is responsible for death. Since we cannot reliably identify susceptible infants, many apparently healthy babies, only a small fraction of which will die of SIDS, are needed to test the efficacy of an intervention which should detect a near terminal event, such as respiratory or heart failure. To be sure of the efficacy of a monitoring intervention, a pilot trial is necessary. Grant proposals for pilot trials of two different types of infant monitors will be reviewed this summer and hopefully they will be of sufficient merit to be funded (one in FY 1989 and the other in FY 1990). These pilot trials will determine: the feasibility of conducting the large-scale clinical trial, the best way to go about conducting such a trial, and the physiologic changes that occur in infants that have life-threatening events.

PERINATALLY ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Question. I understand that the Institute has a clinical trial underway for the treatment of children with AIDS. I understand that 235 children, or almost half of those in the country with AIDS, are involved in this trial. Could you describe for the Committee what progress is being made in the treatment of children with AIDS.

Answer. The NICHD has structured a network of medical centers to study a specific question, namely whether intravenous gamma globulin (IVIG) prevents serious, life-threatening secondary infections in HIV-infected children. This study now involves 29 centers and more than 270 children who are HIV-infected and symptomatic.

With regard to the question of numbers of children with AIDS in clinical trials, the distinction between an infected child and a child with AIDS must be made. AIDS is the most severe stage of HIV infection. However, a child who is HIV infected and has symptoms may not yet have full-blown AIDS. Therefore, the NICHD clinical trial includes both HIV-infected children with AIDS and HIV-infected children who are symptomatic but do not yet have AIDS.

To date, there have been approximately 1,100 children with AIDS reported to the CDC. More than 50 percent of these children are dead. Therefore, it is reasonable to estimate that there are about 500 children living with AIDS in the U.S. who have been reported to the CDC (although there are many-fold more with HIV infection who do not yet have AIDS). Approximately one-third of the children (about 100) in the IVIG study have AIDS. Therefore, approximately 20 percent of children with AIDS in the U.S. who are living are in this study.

In addition to the NICHD, two other Institutes at NIH are active in pediatric HIV therapeutic research: 1) The National Cancer Institute primarily investigates the safety of newly developed agents in infected children; these Phase I studies are the initial evaluation of the use of specific drugs in infants and children; and, 2) The National Institute of Allergy and Infectious Diseases has established an AIDS Clinical Trials Group (ACTG), a standing network of universities and medical centers which test the efficacy and safety of anti-HIV drugs in children and adults; a major component of the ACTG is a group of units specifically devoted to pediatric and obstetric therapeutic research.

In order to fully coordinate all pediatric therapeutic research in the NIH, all three Institutes meet regularly with each other and other interested agencies (e.g. FDA) to coordinate activities. In FY 1990, the pediatric centers in the IVIG study and the ACTG will join together into one single therapeutic research group.

Currently many studies are underway. The NICHD study of intravenous gamma globulin is close to recruiting the 366 children required to complete the study. NCI has already completed the necessary Phase I evaluation of AZT in children given by continuous I.V. infusion. NCI also is studying the various routes by which AZT can be administered. They are also evaluating or planning to evaluate several other agents (e.g. ddI in children). The NIAID is completing a study of the efficacy of orally administered AZT in children. They are also completing the Phase I evaluation of AZT in newborns and will soon begin the Phase I evaluation of AZT in pregnant women.

ENDOCRINOLOGY RESEARCH

Question. Could you provide a breakdown of the amount of endocrinology research being conducted in dollar figures within NICHD and NIH-wide?

Answer. The NICHD supports research in endocrinology as follows: FY 1988 actual obligations were $105,283,000; FY 1989 estimate, $112,000,000; FY 1990 estimate, $115,700,000. Comparable amounts for all of NIH, including NICHD, are: $676,883,000, $714,702,000, and $736,235,000, respectively.

CONTRACEPTIVE DEVELOPMENT

Question. In your opening statement you mention an immuno-contraceptive vaccine that has resulted from your contraceptive development initiative. Is the initiative focused on the development of new contraceptive products?

Answer. The development of new methods is a major objective of the initiative. In addition, it includes basic biomedical research that will give us new knowledge about reproductive processes and may provide leads for the development of contraceptive methods. It also includes studies of the safety and effectiveness of contraceptive methods and research on behavioral aspects of contraceptive use to improve our understanding of the motivations to use or not use contraception when pregnancy is not desired.

Question. Which experimental products or methods are closest to being ready for general use?

Answer. The methods closest to becoming available for general use, if they are approved by the Food and Drug Administration, are the disposable diaphragm, subdermal implants, and spermicides with potent antiviral and spermicidal activity. In addition, we are studying various long-acting methods for men and women, but these are unlikely to be generally available in the near future.

Question. What are some of the other major aspects of the contraceptive development research initiative?

Answer. The Contraceptive Evaluation Branch is supporting a study of the metabolic effects of progestins that are used in contraceptive pills in England to determine whether they are safer than those used in the United States. This Branch is also participating in a 13-country study of new-generation contraceptive pills to document the extent to which they reduce the risk of cardiovascular disease. If, in any of these studies, a foreign formulation is shown to be safer than the formulations available in the United States, it will facilitate FDA approval and make such compounds available for general use here. In addition, this Branch is supporting research to see whether antibiotic prophylaxis at the time of insertion will make IUDs more generally acceptable. The Demographic and Behavioral Sciences Branch is also participating in the Contraceptive Development Initiative by supporting studies on the motivation to use contraceptives and factors affecting the choice of contraceptive methods, both among adults and teenagers.

Question. Is all of the research in contraception based on new or improved drugs and devices? Shouldn't we also be studying what people know about regulating their own fertility and protecting themselves against diseases?

Answer. Clearly the use of methods of contraception requires motivation on the part of the user, correct knowledge about use, understanding of the risks of pregnancy and disease and access to services and supplies. In addition to our biomedical research program to increase the range of available methods, we have an active behavioral research program addressing the many aspects of use of methods. In the past the NICHD program has supported numerous studies on contraceptive decision-making, consistency of contraceptive practice, and contraceptive switching among both adolescent and adult women. In the past year, several studies have been initiated which are expressly focused on the links among sexual behavior, contraceptive decision-making and sexually transmitted diseases. A Request for Grant Applications recently focused attention on the condom as a method of contraception and protection from disease. This is specifically designed to answer the question of what factors motivate people to use this method correctly and effectively. Additionally, as part of our AIDS initiatives, we developing procedures for a national survey of sexual behavior This study addresses research issues related both to the transmission of disease and to contraception. Now, more than ever, it is important to understand how people integrate their concerns and needs regarding contraception with those relating to the prevention of disease.

Question. What do your studies show about the safety of the pill for women?

Answer. The general well-being of women does not appear to be affected adversely overall by use of the oral contraceptive. There are no studies indicating that women who have used the pill, as a group, have a lesser general health status or longevity in any way. In fact, contraceptors as a group, because they may be self-selected on the basis of their excellent health, have demonstrated lower mortality rates in several studies supported by the Institute.

Nevertheless, studies continue to demonstrate that the patterns of illness may be affected by use of the pill. Several studies have shown that the cardiovascular risk factors have been reduced by lowering the dosage of estrogens and progestins in the pill. Studies are underway to show the degree to which cardiovascular side-effects have been reduced from their previously documented low levels. More recent attention has been given to the cancer risks of the pill.

Users of the pill have been clearly shown to have 10-60 percent less ovarian cancer and 10-50 percent less endometrial cancer than women who have never used the oral contraceptive. These protective effects appear to be conferred for life, particularly for ovarian cancer, even after short term pill use. A recent study of the national breast cancer rates in the U.S. suggested that their continuing rise has not been affected by oral contraceptive use. This has been backed up by several studies showing that the first generation of pill users of the 1960's-70's, largely consisting of women in their 20's and 30's at the time, have not demonstrated an increased risk of breast cancer compared to women never exposed. However, several recent contradictory studies have demonstrated a need to restudy this issue in very young pill users, more typically seen in the 1980's. Still, considering all cancers together, the data suggest that the pill may have an overall cancer-sparing effect.

Question. Can you tell us more about the reasons for using spermicides in conjunction with condoms? Why is this important for reasons other than prevention of pregnancy?

Answer. Recent studies have shown that all spermicidal agents, including the American marketed nonoxynol-9 and octoxynol, inactivate many common sexually transmitted diseases in the test tube. Clinical studies have further demonstrated this effect in women at high risk for gonorrhea and other common diseases.

Preliminary laboratory studies of these spermicides against human immunodeficiency virus also show a strong virucidal effect, and it is suspected that spermicides may reduce one's risk of contracting the virus that causes AIDS. Spermicides are considered to be a backup protection when used with condoms because they may still inactivate the virus if a condom slips or breaks. An additional reason to use spermicides is that they are maximally effective against herpes and other sexually transmitted diseases which are themselves risk factors for acquiring AIDS.

Question. What are the most common reasons for infertility in both men and women?

Answer. Reliable data are sparse regarding infertility and, based on the progress of our current research efforts, specific reasons are identifiable in only about 80-85 percent of infertile couples. In the remaining 15-20 percent of such couples, no specific diagnosis is obtained and effective therapeutic protocols are currently not possible. In infertility for which a cause can be found, roughly 40 percent is due to a male factor, 40 percent to a female factor, and 20 percent to a combination of factors. Among female infertility patients, 20-25 percent will have a problem associated with ovulation, 20-30 percent tubal or peritoneal problems, and 5-10 percent a cervical factor. Many of the remaining women with no clear diagnosis have endometriosis. Endometriosis has proven to be a frustrating medical problem because of its high incidence and the incompleteness of our knowledge of its role in infertility. The leading causes of male infertility are disorders of sperm production, obstruction of the sperm transport tract, and varicocele (a collection of large veins in the testes). In the explainable cases, endocrine disorders or other systemic diseases are usually responsible. Unfortunately, in most cases of male infertility, a cause cannot be found.

Question. What is the outlook for couples who want to have children but have been unsuccessful in achieving a healthy pregnancy? What are you studying to help these people?

Answer. Certain forms of infertility are very readily treated. Many cases of failure to ovulate, for example, can be treated with hormone replacement, suppression of abnormal hormone excess (prolactin, androgen), or stimulation of the body's own hormonal mechanisms. The parallel situation in the male, absent or deficient testis-stimulating hormones, is also easily treated. Other possible causes of infertility are much less straightforward, and it is difficult to predict success because the underlying processes are not well understood. Some of these include endometriosis, immune infertility, and varicocele (a collection of large veins in the testes). Some problems such as primary gonadal failure, remain completely resistant to medical or surgical treatment at this time. The Reproductive Sciences Branch of the NICHD supports research on ovulation defects and other abnormalities of the menstrual cycle, hormonal excess or deficiency, endometriosis, abnormalities of gamete (egg and sperm) maturation and function, immunologic infertility, tubal (gamete transport) disease, abnormal sperm-egg interactions, and early (peri-implantation) pregnancy loss. Research is also supported on improved technology and testing procedures related to the diagnosis and treatment of infertility.

Question. Where is all of this kind of research done? With limited resources, how do you coordinate sophisticated research on such a varied subject as reproductive medicine?

Answer. Assistance is provided to academic institutions, medical centers, hospitals, institutes, and small businesses across the U.S. and to a few foreign sites. In addition to the regular research grants, the Population Specialized Research Center Grant and Center Core Grant programs provide a multidisciplinary

environment for collaborative research. These Centers form a network that fosters communication, innovation, and high-quality research. The Branch is currently requesting applications for participants in a multicenter Reproductive Medicine Network. This Network will plan and carry out large-scale clinical trials under a group of Cooperative Agreements between the grantee institutions and the NICHD. Through NIH-wide computer data bases, the NICHD is also able to monitor research projects in other NIH Institutes which may be relevant to infertility. The staff scientists of our Reproductive Sciences Branch are responsible for working closely with our national network of extramural scientists to pursue infertility research of high priority in the most cost-effective manner.

Question. Can you support all of this research in 1990 with fewer numbers of grants and amounts for individual awards that are reduced substantially from the recommended levels?

Answer. The NICHD will be able to continue a very significant and productive program in FY 1990, supporting the highest priority research project grants. Downward negotiations in FY 1990, currently estimated at 10.2 percent for competing projects and 14.2 percent for noncompeting grants, are comparable in size to the downward negotiations being experienced in FY 1989.

RESEARCH PROJECT GRANTS

Question. NICHD's 1990 budget request (exclusive of AIDS funding) represents an increase of $13,432,000, or 3.3 percent, over 1989. How many new and competing research grants and clinical trials does it plan to fund at this budget request level?

Answer. The NICHD will fund 341 new and competing renewal research project grants in FY 1990. The Institute expects to continue funding approximately 100 clinical trials for $35,800,000 in FY 1990. There will be no new, major clinical trials in FY 1990, however.

Question. What new research projects or clinical trials would NICHD support with the requested funding level?

Answer. The NICHD will fund some 189 new research project grants in FY 1990. The NICHD determines which new grants will be funded after the peer review process is complete. So it is not possible at this time to identify specific new research project grants to be funded next year. The major NICHD programs, Population Research, and Research for Mothers and Children, will fund a variety of new projects in FY 1990, encompassing such vital program areas as prevention of low birth weight and infant mortality, sudden infant death syndrome, mental retardation, childhood injuries, birth defects, fertility regulation, infertility, reproductive diseases, and behavioral studies on the use of contraceptives. The Institute is not planning to begin any major new clinical trials in FY 1990.

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question. What new information about the cause(s) of Sudden Infant Death Syndrome is provided in the recent report

(February 1, 1989) by a committee of experts in the field of sudden infant death?

Answer. The experts synthesized a conceptual framework for SIDS--that an infant who succumbs to SIDS has an underlying vulnerability and that death can be triggered in these infants by one or more external stresses that characterize its new life ex-utero. Therefore, scientists must delineate what these vulnerabilities are and how the triggers induce death. From the NICHD SIDS Cooperative Epidemiologic Study we have learned that newborn apnea is not necessarily a marker for an infant destined to die of SIDS as was once thought. Newborn apnea occurred very infrequently in fullterm babies who succumbed to SIDS. SIDS babies were more likely to have low levels of oxygen in their system and excessively rapid heartbeats in the neonatal period, and mild respiratory tract infections, diarrhea, or vomiting in the two weeks preceding death. In addition, it was found that childhood vaccination does not trigger a SIDS death.

The report also described some of the recent findings which are keys to unlocking the underlying vulnerability of SIDS infants. Researchers supported by the NICHD have shown that infants destined to die of SIDS have higher heart rates at one month of age than babies who survived. These infants also exhibit disturbed patterns of coordination between respiration and heart rate during sleep/waking states.

A few research projects supported by NICHD are searching for structural and chemical abnormalities in SIDS victims which may be responsible for altered control of cardiorespiratory function during sleep. These investigators are focusing on neurotransmitter receptors in the brain stem, the area of the brain which integrates the processing of external stimuli, cardiorespiratory function, and sleep. They have found that these structures change with development and are altered in some SIDS victims.

It is estimated that between two and five percent of SIDS cases are actually death from an inherited disorder of fatty acid metabolism that does not produce symptoms until an infant is stressed. At that time the infant rapidly succumbs. Techniques have now been developed to detect a baby with this disorder in families that have a suggestive family history, i.e. previous victims of SIDS or Reye's Syndrome. The NICHD is currently supporting research which is confirming the possibility that some SIDS victims have substantial metabolic abnormalities consistent with other inherited metabolic disorders. In addition, we are funding research to uncover new metabolic disorders that may be contributing to unexpected and unexplained death in the infant.

LOW BIRTH WEIGHT AND INFANT MORTALITY

Question. Experts agree that this Nation's infant mortality rate probably will not drop significantly further until there is a reduction in the incidence of low birth weight. What percentage of NICHD-supported research is devoted to determining specific biological or behavioral causes of low birth weight?

Answer. In FY 1988, NICHD obligations for research in the area of preventing low birth weight were $50,162,000 of a total non-AIDS comparable budget of $379,646,000, or 13.2 percent.

Question. The birth of any given low birth weight child may be due to prematurity and/or intrauterine growth retardation. Is there any evidence which suggests that one or the other is more strongly associated with low birth weight? If so, please specify.

Answer. The low birth weight infant may indeed be born before term or be a full term baby who is underweight for gestational age. The causes of low birth weight are not totally understood, and, therefore, the evidence implicating either prematurity or intrauterine growth retardation is not available. It has been noted that within the inner city population, a greater number of low birth weight infants are growth retarded in utero rather than premature. The latter seems to indicate that conditions associated with this specific high-risk population influence fetal growth. More studies are needed to definitely identify causes of low birth weight and design appropriate interventions.

Question. What new insights have evolved regarding the reasons for prematurity? The same question could be asked about reasons for intrauterine growth retardation.

Answer. Various leads are being pursued to clarify the process(es) resulting in premature labor and delivery. But, the initial step or triggering event for both term and preterm labor remains elusive. Promising findings are being uncovered regarding the potential role of certain maternal infections as initiators of preterm labor.

A significant research expansion has occurred in the area of intrauterine growth retardation, regarding among other aspects, the potential interrelationships among fetal growth factors, maternal nutritional status, and maternal medical problems known to be associated with low birth weight.

Question. What preliminary conclusions have studies supported by NICHD reached regarding the effects of maternal smoking, alcohol consumption, and illicit drug use on pregnancy outcomes or infant mortality?

Answer. The NICHD has supported numerous investigations on the effects of smoking, alcohol and illicit drug use on pregnancy outcomes. Women who smoke up to one-half pack of cigarettes per day during pregnancy have been shown to be approximately 50 percent more likely than non-smokers to give birth to a low birth weight infant (less than 5 1/2 pounds). Women who smoke more than one-half pack are over twice as likely to give birth to a low birth weight infant. Heavy smokers are also more likely to deliver early, particularly regarding births that are more than two months premature. Infants of mothers who smoked were more likely to die during their first year of life, particularly from respiratory diseases and sudden infant death syndrome (SIDS).

Heavy alcohol consumption during pregnancy (more than 6 drinks per week) puts women at increased risk of experiencing a

miscarriage. Moderate consumption of alcohol during pregnancy has also been associated with a reduction in birth weight and a 66 percent increase in the risk of low birth weight.

In an NICHD study of inner-city women, use of cocaine, heroin, marijuana, or other illicit drugs during pregnancy was associated with a six-fold increase in the risk of low birth weight.

DOWN SYNDROME

Question. The presence of an extra chromosome 21 is associated with the occurrence of Down Syndrome. NICHD is supporting several projects on gene mapping of chromosome 21. What implications do the identification and localization of the genes on this chromosome have for prevention or treatment?

Answer. Identification and localization of genes on chromosome 21 will give scientists an opportunity to clone those genes, characterize their molecular structure, insert one or a combination of those genes in newly fertilized mouse egg and then to evaluate the effects of an extra dose of a given gene on the developing embryo. Since there are genetic similarities between human chromosome 21 and mouse chromosome 16, this animal model could be used to study the embryology, anatomy, biochemistry, and development of trisomy 16 mice which otherwise could not be carried out on human subjects. If a gene or a combination of genes on chromosome 21 are found to be responsible for Down syndrome, initial attempts could then be made to remove or immobilize the extra gene and ascertain whether normal mice could be produced.

AIDS

Question. In last year's appropriations hearings, NICHD differentiated between pediatric AIDS and reproductive AIDS. What is the difference between pediatric AIDS and reproductive AIDS?

Answer. The large majority of women with AIDS in the U.S. are of reproductive age and capability. Reproductive or maternal AIDS refers to those infected women who become pregnant and give birth. Pediatric AIDS refers to the most severe form of HIV infection in children less than 13 years of age. Three-quarters of AIDS in children results from a mother who is infected and transmits her infection to her child during pregnancy and/or delivery. Thus, maternal (or reproductive) AIDS and pediatric AIDS are separate problems and yet problems which are intimately linked. Maternal (or reproductive) AIDS involves many research issues and questions including: 1) how does HIV infection affect the outcome of pregnancy; 2) how does pregnancy affect the course of HIV disease in infected women; 3) how can future pregnancies be prevented in infected women; 4) how can sexually active infected women be educated to prevent transmission of HIV infection to their sexual partners; and, 5) what factors influence transmission of HIV infection from mother to child.

Pediatric AIDS involves many research issues and questions including: 1) what distinguishes the infected child who becomes symptomatic from the child who remains asymptomatic; 2) what are

markers of progression of disease in children; and 3) what treatments will prove effective in infants and children.

Question. In NICHD's FY 90 request for AIDS funding, what percent is targeted for pediatric AIDS?

Answer. The FY 1990 NICHD request for Pediatric AIDS is $22,000,000, which is 81.1 percent of a total AIDS request for NICHD of $27,129,000.

Question. NICHD researchers have reported that almost 1/3 of all HIV infected mothers who give birth transmit their infection to their child. What does research indicate regarding the percentage of these children who will develop AIDS or HIV-related disease?

Answer. NICHD investigators, working together with NCI researchers, have determined in a preliminary analysis of the data that the rate of transmission is approximately 33 percent. In this study, 30 infants born to HIV infected mothers were followed for more than one year, and 10 were found to be infected. Seven of these 10 infants had CDC-defined AIDS; 2 were very symptomatic with failure to thrive and other serious problems. Only one was currently asymptomatic but had laboratory evidence of immunosuppression. Many researchers believe that eventually all HIV-infected children will go on to die of AIDS. It is safe to say that the vast majority of perinatally infected children will go on to develop and die of AIDS.

Question. NICHD-supported research shows that at certain concentrations, various spermicides can inactivate HIV in vitro and kill lymphocytes in vitro. What plans are underway to assess the effectiveness of spermicides as a means of HIV transmission prevention?

Answer. In vitro research on the effectiveness of spermicides against free and cell born HIV is still preliminary, and these experiments must be repeated. The NICHD will issue a request for grant applications to be funded in 1990 to restudy this issue. Experimental models will be funded which demonstrate the degree to which spermicides affect the transfer of HIV from infected human mononuclear cells to susceptible culture cells. Similar models will be funded using free virus.

QUESTIONS SUBMITTED BY SENATOR ERNEST F. HOLLINGS

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question. How many babies die each year of SIDS? Is this number increasing or decreasing?

Answer. Between 6,000 and 7,500 babies die from SIDS annually in the United States. This number has not changed significantly over the last few years.

Question. Are we any closer to knowing the actual cause of SIDS?

Answer. We have a conceptual framework for SIDS--that an infant who succumbs to SIDS has an underlying vulnerability that can be triggered by one or more external stresses that characterize its new life ex-utero. This underlying vulnerability is most-likely a product of the fetal period. Therefore, scientists must delineate what these vulnerabilities are and how the triggers induce death.

There are probably multiple triggers that lead to SIDS. Scientists have identified one inherited disorder of fatty acid metabolism that accounts for at minimum two percent of the cases that have been diagnosed as SIDS. Death from this metabolic disorder can be prevented with a simple diet supplement.

For the majority of SIDS deaths, however, we do not know the trigger or cascade of events that lead to death. Our knowledge has increased regarding potential causes of death in these infants by studying apnea and cardiorespiratory function in developing animals. These studies tell us that at certain critical postnatal periods, young animals are more susceptible to death from hypoxia than others, and if deprived of oxygen chronically do not arouse when they achieve life-threatening low levels of oxygen in the blood. We are also learning how neurochemicals control these responses and how their imbalance could lead to death.

Of great significance are the subtle differences in physiology and nervous system structure and composition that differentiate a SIDS baby from one that lives. Many of the studies on autopsy material from SIDS victims began in the last two to four years. These are just beginning to bear fruit and are providing clues as to SIDS related abnormalities in the parts of the nervous system that control respiration, heart rate and these functions during sleep. By several structural and chemical criteria, the brains and peripheral nervous systems of SIDS infants appear immature or show evidence that they may have been exposed to a chronic hypoxic insult. Some SIDS infants show greater abnormalities than others. These studies of the nervous system imply that a SIDS infant's vulnerability to postnatal stresses is induced in the fetal period, probably by several different mechanisms.

Detailed analyses of recordings of respiratory and cardiac physiology during sleep of infants who eventually died of SIDS and SIDS siblings support the autopsy results. With the aid of sophisticated computer technology developed under NICHD funding, differences have been revealed between these babies and normal infants. Heart rate and the coordination of respiration and heart rate during sleep in one month old infants destined to die of SIDS were observed to be different from infants who lived. However, the range of measures overlap with living babies so they cannot be used to identify a baby at high risk for SIDS.

Since SIDS babies die during sleep periods, most likely from cardiac and or respiratory arrest, these are important findings. However this research must be continued and expanded.

Question. What else are you going to study? What will you look for next to prevent this terrible problem?

Answer. Scientists need more data to understand the differences among SIDS babies, and between SIDS babies and normal

infants. We do not have enough information on normal infants development to know the range of variability in the regulation of cardiorespiratory, nervous, and immune function that is tolerated by normal infants, and when the line is crossed to make an infant vulnerable. Therefore, we need to expand research in normal development of the brain, cardiac, respiratory, and immune systems, and the behavioral and physiological response of infants to normal life stresses.

Research on infant physiology and development will require parallel studies to develop and test new technologies for monitoring the behavior and nervous system maturity of infants. In addition, these new technologies may be used to detect infants at risk and to monitor them when testing an intervention.

We plan to develop more specific animal models for SIDS to perform basic biological studies at critical times in development, to develop prognostic tests, and for pre-clinical testing of therapeutic and preventive interventions.

We need to obtain information on the terminal events preceding death by developing and testing home monitors with permanent recordings of physiological parameters. In addition, it is important to assess the efficacy of home monitors that detect the relevant physiological parameters in preventing SIDS. Two such studies are planned.

Since SIDS babies die primarily during sleep periods and we have evidence that their regulation of cardiorespiratory function is abnormal in sleep/waking states, we must expand our study of sleep states in normal, at-risk, and SIDS infants.

We plan to expand research in potential metabolic disorders that make infants vulnerable to sudden death and to develop screening procedures for relevant disorders. The screening technology is being developed and looks very promising.

We plan to expand epidemiologic studies on specific risk factors for SIDS such as prematurity, intrauterine growth retardation, and maternal smoking so that we can design better preventive strategies and understand what insults in the fetal period make an infant vulnerable to SIDS.

Question. Are these new kinds of studies included in the SIDS Five-Year Research Plan that you submitted to the Congress recently?

Answer. Yes. These studies are outlined in the implementation plan of the SIDS Five-Year Research Plan.

Question. How much are you spending for SIDS research in 1989? What is your request for 1990?

Answer. In FY 1989, NICHD total obligations for SIDS research are estimated at $35,200,000, and for FY 1990, $36,500,000.

Question. Are there additional worthwhile studies that you could support beyond the amount you request for 1990 if additional funds are available? What are these studies?

Answer. Yes. These studies are outlined below and are in the implementation plan of SIDS Five-Year Research Plan.

- Pilot clinical trial of home monitors: A proposal for a pilot clinical trial of a very promising oxygen monitor that may detect an hypoxic infant in time for resuscitation has been submitted to NIH.

- SIDS Registry, Tissue Bank, and Medical Examiner Support: We would like to set up a national registry and tissue bank to provide investigators with well characterized and preserved autopsy specimens from SIDS victims and controls that are matched for a variety of characteristics.

- SIDS Risk Factors: To gather more information on risk factors for SIDS, such as smoking and drug abuse during pregnancy, we plan to convene a workshop regarding predictive factors for SIDS and to develop interagency agreements with other federal agencies to initiate the research.

- Animal Models for SIDS: Animal models are needed to search for the basic mechanisms of SIDS that are probably initiated in utero, to design tests for prognostic markers for SIDS, and for pre-clinical testing of interventions. We need to expand our models beyond those that are currently funded and to stimulate research in models that mimic SIDS.

- Immune Response in Normal and At-risk Infants: SIDS victims show evidence of infections prior to death and a unique immune response in the lungs. Our knowledge of the normal infant's immune responses is limited, particularly in relation to its interaction with cardiorespiratory function. We know even less about the development of the immune system of infants who are at high risk for SIDS, i.e preterm, small for gestational age. In FY 1990 we plan to hold conferences which will help to define the research that is needed in these areas. The request for grant proposals will be developed in FY 1990 and funding would take place in FY 1991.

Question. What amounts for SIDS research are projected in your five-year plan for the years beyond 1990? What is your judgment of SIDS research funding needs through 1993?

Answer. The SIDS five-year plan consisted of detailed recommendations for research on SIDS, but did not contain funding projections. The professional judgment of the NICHD for SIDS funding for the research activities that are recommended in the plan are: FY 1990, $11,000,000; FY 1991, $21,000,000; FY 1992, $28,000,000; and, FY 1993, $30,000,000.

QUESTION SUBMITTED BY SENATOR DANIEL K. INOUYE

INFANT DAY CARE

Question. Dr. Alexander, I first want to commend you on your initiative in the area of the effects of non-parental infant day care on child development. With half of all mothers with infants working outside the home, this research is critical and timely.

Please tell us about your plans for this research and, in your professional judgment, if sufficient funds are available to support this vital work.

Answer. The NICHD has begun a major initiative in the area of child day care research. In FY 1989, a network of 6 child day care research units will be funded. This network will provide information on the relationship between the family environment and alternate child care to the cognitive, social and emotional development of children in the first 42 months of their life. This will be accomplished by collecting information about a total of 1,200 children. The information will be collected in different sites under a common research protocol. That is, all families, care situations and children will be evaluated by the same criteria. In addition, each research unit will choose to collect additional, more detailed information about some aspects of the common research protocol. For example, one unit may choose to characterize emotional development in greater detail, while another may focus more on the description of mother-child interaction.

The units will also vary in terms of the type of families sampled, such as subsamples of single mothers or of intact families living in poverty. The units will focus on different types of care, including care in the home of a relative, care by a sitter who comes to the child's home, or care at the home of an unrelated care giver.

The FY 1990 budget request would support the six units established in FY 1989. The professional judgment of the NICHD is to fund a total of 10 units. The additional cost in FY 1990 would be $1,000,000 for four more units. With 10 units in the network, the representation of socio-economic background, types of families, types of care, and detailed aspects of child development will be more comprehensive than with 6 units. In addition, from a statistical point of view, the study would be stronger with 10 units because of the larger number of children included.

QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

CHILD HEALTH RESEARCH CENTERS

Question. Dr. Alexander, I understand there are a number of pediatric clinical/academic institutions across the country, particularly in Pennsylvania, that could make a significant contribution to pediatric research through a national program of child health research centers. In your professional judgment, is there a need for such a program?

Answer. We have had discussions with people in the pediatric community and I believe, as they do, that there is a need for this program. The child health research centers would further the goal that children share fully in the advances coming from medical research and that these advances are translated as rapidly as possible to improve care for them. The pediatric community has told us that support is needed for centers of excellence in pediatric research, for laboratories where young pediatric investigators can be trained, and where research results can be translated to the bedside.

Question. How much would be adequate to launch such a program?

Answer. We could have an excellent network of approximately 15 child health research centers for $10,000,000 in FY 1990.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

SUDDEN INFANT DEATH SYNDROME (SIDS)

Question. How many infants die of Sudden Infant Death Syndrome (SIDS) annually? What is the trend in incidence over the last decade? Are there any regional variations in incidence?

Answer. Between 6,000 and 7,500 infants die from SIDS annually in the United States. The actual number of SIDS cases has declined slightly over the last decade, but, when reported as the proportion of infant deaths, it has increased from 11.6 percent to 13.6 percent. Although the incidence of SIDS varies from 1 per 1000 live births to 2.8 per 1000 live births as reported by each state, it is difficult to know whether this reflects a true difference in incidence or a difference in diagnosis and reporting.

Question. What SIDS research did the NICHD support in FY 88, in FY 89 and what do you expect to support in FY 90? Are we closer to knowing the cause of SIDS?

Answer. In FY 1988, NICHD support for SIDS was $30,381,000. Estimates for FY 1989 and FY 1990 are $35,200,000 and $36,500,000, respectively.

The research projects supported in FY 1988 and FY 1989 involve animal models for studying the development of the cardiorespiratory centers, the effects of chronic hypoxia on cardiorespiratory function, and the mechanisms of arousal from sleep and recovery from apnea; detailed analyses of the cardiorespiratory patterns and sleep states of infants destined to die of SIDS; searches for metabolic defects in autopsy tissue of SIDS infants and in infants at high risk for sudden death; detailed structural and chemical analyses of the central nervous system and peripheral nervous system of infants who succumbed to SIDS; a prospective analysis of the cry characteristics of infants that may distinguish SIDS babies prior to death; and, a comparative analysis of fetal hemoglobin levels in SIDS infants and controls to confirm reports that abnormal fetal hemoglobin levels could serve to identify infants prior to death. In addition, we have an interagency agreement with the Armed Forces Institute of Pathology to maintain the tissue specimens derived from the infants studied in the NICHD SIDS Cooperative Epidemiological Study. A SIDS Histopathology Atlas has been generated from this specimen bank. This atlas will serve as a reference for general and forensic pathologists to guide them in classifying a death as SIDS.

Intramural NICHD scientists in FY 1988 studied apnea in infants and rats, and were able to delineate the physiological changes associated with apnea as well as to perform detailed pathology on the rats who succumbed. The pathology is very similar to that of SIDS victims and suggests that the inflammatory response in the lungs may precipitate shock in infants and lead to a fatal apneic event.

The Cause of SIDS: These studies are bringing us closer to understanding what can trigger sudden death, what are the mechanisms for death in SIDS infants, and how SIDS infants are distinct from babies that do not die. At certain critical postnatal periods, young animals are more susceptible to death from hypoxia than others, and if deprived of oxygen chronically do not arouse when they achieve life-threatening low levels of oxygen in the blood. We are also learning how neurochemicals control these responses and how their imbalance could lead to death.

Many of the studies on autopsy material from SIDS victims began in the last two to four years. These are just beginning to bear fruit and are providing clues as to SIDS related abnormalities in the parts of the nervous system that control respiration, heart rate, and these functions during sleep. By several structural and chemical criteria, the brains and peripheral nervous system of SIDS infants appear immature or show evidence that they may have been exposed to a chronic hypoxic insult. Some SIDS infants show greater abnormalities than others. These studies of the nervous system imply that a SIDS infant's vulnerability to postnatal stresses is induced in the fetal period, probably by several different mechanisms.

Detailed analyses of recordings of respiratory and cardiac physiology during sleep of infants who eventually died of SIDS and SIDS siblings support the autopsy results. With the aid of sophisticated computer technology developed under NICHD funding, differences have been revealed between these babies and normal infants. Heart rate and the coordination of respiration and heart rate during sleep in one month old infants destined to die of SIDS were found to be different from infants who lived. However, the range of measures overlap with living babies so they cannot be used to identify a baby at high risk for SIDS.

Since SIDS babies die during sleep periods, most likely from cardiac and or respiratory arrest, these are important findings. However this research must be continued and expanded. Scientists need more data to understand the differences among SIDS babies, and between SIDS babies and normal infants. We do not have enough information on normal infant development to know the range of variability in the regulation of cardiorespiratory function that is tolerated by normal infants, and when the line is crossed to make an infant vulnerable.

In FY 1990 we will continue these projects and would like to support a clinical trial of a monitor that may detect an hypoxic infant in time for resuscitation. The support of the project will depend on the outcome of the peer review of this proposal and the availability of funds.

New research initiatives in FY 1990 would be developed according to the implementation plan of the SIDS Five-Year Research Plan that was submitted to Congress and will depend on additional funds. We would like to set up a national registry and tissue bank to provide investigators with well characterized and preserved autopsy specimens from SIDS victims and controls that are matched for a variety of characteristics. It is very difficult to obtain material from the appropriate control infants. This is hampering the progress of SIDS research. As mentioned above, the

heterogeneity of abnormalities observed in SIDS infants, and our limited knowledge of normal infant development, makes it necessary to study a large number of infants. Many new and sensitive technologies are available to examine tissues; some of these are being developed by SIDS investigators. Two research conferences are being planned in conjunction with the registry and tissue bank initiatives. One will be held on June 20, 1989 and will focus on updating the definition of SIDS for research purposes, and setting guidelines for scientists in classifying specimens and choosing the appropriate controls. The other conference, planned for FY 1990, will bring scientists together to discuss the sophisticated technologies that can be used to examine autopsy material and how they can be used to further SIDS research. In addition, we plan to increase the utilization of the specimens from the NICHD SIDS Cooperative Epidemiological Study by inviting visiting scientists to work with the collection on site, and through a specific request for research grant applications for studies to be conducted in other scientists' own laboratories. These pathology studies will capitalize on the defined epidemiological characteristics of the specimens.

To gather more information on risk factors for SIDS, such as smoking and drug abuse during pregnancy, we plan to convene a group of federal program officers responsible for ongoing epidemiology studies or existing databases of infant mortality and infant morbidity. This workshop will determine whether information regarding predictive factors for SIDS can be obtained from these studies and develop interagency agreements to initiate the research.

There are two other important areas of research that require expansion: Animal models for SIDS and the development of immune responses in normal and at risk infants. Animal models should be expanded beyond those currently funded to include models that mimic SIDS. Some SIDS victims show evidence of infections prior to death and a unique evidence of immune response in the lungs. These observations must be pursued in the context of greater knowledge of the developing immune responses of an infant. In FY 1990 we plan to hold conferences which will help to define the research that is needed in these two areas. Funding of specific initiatives will take place in FY 1991.

Question. Last year the Committee requested the NICHD prepare and submit a report detailing a five-year SIDS research plan. I note, with appreciation, the Institute completed the plan and submitted it to the Committee in February of this year. How much of the five-year plan does the Institute expect to implement under the President's budget recommendation? Are there additional studies that you could support beyond those included in the FY 90 budget if more funds were available? What are they and how much would they cost?

Answer. Under the President's budget recommendation, the Institute plans to continue to fund a pilot trial, initiated in FY 1989, evaluating the effectiveness of home monitors to prevent SIDS. In addition we plan to continue to support research grants directly related to SIDS that are currently funded, as well as to support additional investigator initiated SIDS research grants. We also plan to fund one or two visiting scientists to use the collection of autopsy material from the NICHD SIDS Cooperative Epidemiologic

Study. This unique collection of well-defined SIDS tissues will enable scientists to correlate epidemiologic characteristics with biologic qualities of SIDS infants.

The remainder of the studies outlined in the implementation plan will require additional funds. These initiatives and the projected budgets for these are:

(1) Pilot clinical trial of an oxygen monitor which is designed to record the physiology of an infant prior to an alarm event: $3,500,000;

(2) SIDS registry, tissue bank, and medical examiner support for training and tissue acquisition: $3,000,000;

(3) SIDS data acquisition workshop and interagency agreements: $525,000;

(4) Animal models for SIDS: A conference is planned for FY 1990 to delineate the criteria for animal models of SIDS, to discuss the types of new experimental approaches necessary, and to evaluate existing models. Requests for contract proposals will be developed in FY 1990; contracts would be funded in FY 1991. The conference will cost approximately $15,000 and we will need $900,000 in FY 1991 for the animal model contracts; and,

(5) Immune response of normal and at-risk infants: In FY 1990 we plan to hold a conference which will help to define the gaps in our knowledge of the developing human immune system. Requests for grant proposals will be developed in FY 1990 and funding will take place in FY 1991. The conference will cost approximately $10,000 and we will need approximately $2,250,000 in FY 1991 to support grants in this area.

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next, National Eye Institute. Dr. Carl Kupfer.

Dr. KUPFER. Thank you, Mr. Chairman. I would like to present a very brief review of two or three highlights of the last year.

I think one of the most interesting things that has happened is that we can now for the first time begin to approach effectively degenerative diseases of the retina, the seeing part of the eye. Researchers, working with an animal model of the retinal degenerative disease retinitis pigmentosa, have transplanted normal rat retinal cells into a diseased retina, completely halting the degenerative process in the recipient retina.

I think this research has very far-reaching implications, not only for degenerative diseases of the retina but, because the retina is part of the central nervous system, for other degenerative diseases as well.

We have continued to support research on the complications of diabetes in the eye and will soon be reporting the results of a large clinical trial in this area, the Early Treatment Diabetic Retinopathy Study.

We have recently completed an economic analysis of our first diabetic retinopathy trial in which laser treatment was found to be of major benefit in reducing blindness from diabetic retinopathy. A conservative estimate is that over the past 12 years approximately $293 million has been saved, and one can justifiably estimate a figure as high as $1 billion.

Additionally, with the stimulus of the Senate, we have begun a National Eye Health Education Program. A planning meeting was held in March to map our strategies for public and professional education in two areas where these efforts are greatly needed and will be most productive, retinopathy and glaucoma. Our intent is to systematically disseminate information concerning these two diseases on a national basis.

PREPARED STATEMENT

We are also planning to develop demonstration projects that will bring the results of what we know about the treatment of diabetic retinopathy to both the public and the medical professions, and to alert those at high risk for the development of glaucoma to the need for comprehensive eye examinations.

The fiscal 1990 budget request is $233,777,000. I would be happy to answer any questions.

[The statement follows:]

STATEMENT OF DR. CARL KUPFER

Twenty years ago, Congress created the National Eye Institute (NEI) with the mission to conduct and support research on blinding eye disease and visual disorders. In just two decades, Americans, both young and old, have benefitted greatly from this body's foresight in establishing a distinct Federal program to support basic and clinical investigation of the mechanism of visual function and preservation of sight.

For example, within the last decade, NEI-supported vision researchers have found a way to prevent blindness from one form of age-related macular degeneration (AMD) the leading cause of severe visual loss among people over age 60. In its most devastating, neovascular form, weak capillaries develop beneath a very small area of the retina called the macula, which is responsible for sharp, central vision. When these abnormal vessels hemorrhage, light-sensitive cells near them cease to function. In 1982, an NEI-supported clinical trial showed that the argon blue-green laser can be used to treat the weakened capillaries outside the fovea, the area of the macula that provides the most acute vision. This treatment stops the hemorrhaging and helps to preserve sight. Currently, investigators in this study are evaluating whether the krypton laser, which is being used to treat lesions much closer to the fovea, can be effective for treating a broader group of eyes with AMD.

At the other end of the age spectrum, we now have an effective treatment for retinopathy of prematurity (ROP), a disease responsible for 20 percent of blindness among children under 5 years of age. Thanks to modern neonatal care, more very small premature infants are surviving today than ever before, but many are also developing ROP. Last April, investigators from an NEI-supported multicenter clinical trial reported preliminary data showing that for certain infants the incidence of severe retinal damage from ROP can be cut in half by a treatment employing a cryoprobe that briefly freezes a portion of the eye's surface.

When the treatment's success became evident, NEI staff and the trial investigators faced a dilemma: How could they quickly inform physicians who take care of premature infants about the study's findings so that their patients could benefit from them immediately, without jeopardizing later publication of complete study results? The solution was to prepare a clinical alert that briefly outlined study results and included a list of all principal investigators in the study to whom patients could be referred. This alert was mailed promptly to 2,300 pediatric ophthalmologists, retinal specialists, and other physicians associated with neonatal care.

In so doing, we risked having study findings released through the news media before they could be reported in a

scientific journal. Through careful planning and a little bit of luck, this did not occur. Instead, in conjunction with publication of study results in the Archives of Ophthalmology, the study's findings were announced to the public at a well-attended press conference that resulted in extensive national and local media coverage at an appropriate time. Infants in the study will be followed over the next several years to assess the long-term effect of the treatment.

While these and other clinical trials continue to evaluate alternative and new methods of treating retinal degenerations, exciting progress in laboratory research is providing hope that some day we may be able to prevent visual loss from these disorders, both those related to the aging process, like AMD, and those that result from a genetic defect. About 400,000 Americans today have some form of inherited retinal degeneration. Of these, about 100,000 have retinitis pigmentosa (RP). Young people with RP often have severely impaired peripheral vision by their late teens and usually become blind within the next decade.

Retinal degenerative diseases have long posed a major challenge to vision researchers. We can sometimes slow the progression of visual loss from certain retinal degenerative diseases, but we have no way to prevent or cure them. I am happy to report, however, that results from two recent NEI-supported studies provide the first real evidence that future treatment--and even prevention--of these diseases is at last within the realm of possibility.

One group of researchers has taken strips of various retinal cells from newborn rats and transplanted them into damaged retinas of adult rats. More than 90 percent of the transplants survived and continued to develop into the appropriate layers of the retina. Even more significantly, the transplanted cells seemed to integrate with the adjacent host cells.

In the second very creative laboratory experiment, scientists worked with the pigment epithelium (PE), which is a single-cell layer underlying the retina. Research has shown that the PE ensures the proper functioning of the photoreceptors, the light-sensitive cells of the retina, by supplying them with nutrients and removing waste products from them. The PE also helps guide the differentiation of immature nerve cells into mature photoreceptor cells. In one animal model, however, the PE is also the site of the genetic mutation that progressively destroys these photoreceptor cells.

The scientists successfully transplanted normal PE cells from young rats to the damaged areas of the PE of rats that develop a degenerative retinal disease much like human retinitis pigmentosa. The transplanted cells stopped the degeneration and rescued populations of nerve cells that otherwise would have died from the inherited disease.

Research like this may have immense clinical significance. For example, it raises the possibility that one day degenerating retinal cells, or those already lost from hereditary diseases, could be rescued or replaced with healthy cells. Specifically, it may be possible to design cell replacement therapies for inherited diseases like retinitis pigmentosa or for age-related retinal diseases such as macular degeneration.

These laboratory studies point to possible therapies for the future, but other basic research is providing biological insights that may help clinicians anticipate secondary effects of new therapies before they are tested in humans. In the course of isolating and elucidating the structure of various crystallins, the transparent structural proteins that make up 85 percent of the eye's lens, NEI intramural scientists found that families of genes produce proteins that function differently in a variety of body tissues. One gene, for example, produces high levels of a structural crystallin protein in lens cells, while an identical or almost identical sister gene produces a similar protein, an enzyme, that catalyzes a specific biological action in a liver cell. Thus, the researchers have found that a single gene can produce a protein that provides either a structural or enzymatic function, according to the needs of the cell in which it is expressed.

Discovery of this multifunctional nature of crystallins adds significant insights into how genes are conserved in nature, and it provides clinicians with information that may be important for design of effective therapies. For example, the clinician armed with this understanding can better ensure that a drug or gene therapy designed to act on a structural protein in the lens to prevent cataract formation will not adversely affect the function of the same or very similar protein in another tissue like the liver.

In another exciting area of research, progress in combatting eye disorders caused by diabetes has been gaining significant momentum. About 40 percent of the 11 million Americans with diabetes have eye complications. Diabetic retinopathy, the most common and most serious complication, is the leading cause of blindness in American adults under age 60. Even with rigid blood sugar control by insulin or oral agents, approximately 90 percent of diabetic patients develop some retinal lesions after 15 years of insulin-dependent diabetes. Many eventually become blind.

We now have new hope for the eventual prevention of this disease. Recent evidence from many lines of investigation indicates that the ocular complications of diabetes have a single primary cause. What is more important, this chemical cause can be controlled by novel pharmacological agents that act independently of other agents used to control blood sugar levels.

Over many years, NEI research has established that an enzyme, called aldose reductase, has a central role in diabetic retinopathy and other ocular and systemic complications of diabetes. The normally high concentration of aldose reductase in retinal capillaries increases in amount and activity in the diabetic animal models.

Although we have developed treatments that in many cases can slow, halt, and even reverse visual loss from diabetic retinopathy, a major goal of the NEI has been to discover ways to prevent the disease. A primary limiting factor in testing the potential benefit of promising drugs has been the lack of a good animal model for diabetic retinopathy. Now, for the first time, two reliable experimental models have been developed at the NEI that mimic precisely the early lesions typical of diabetic retinopathy in humans. Using both dog and rat animal models of diabetes, NEI researchers have found that degeneration of the support cells and weakening of the retinal capillaries are, in fact, the first structural changes of diabetic retinopathy.

These researchers have now found that by treating the animals with oral inhibitors of aldose reductase, the degeneration of support cells, capillary weakening, and all the subsequent structural aberrations of diabetic retinopathy are stopped. Three different inhibitors, representing two structurally distinct chemical groups, are effective. Aldose reductase inhibitors are the first class of drugs shown to be beneficial for the treatment of diabetic complications that are unaffected by therapies such as insulin and oral agents that are used to control blood sugar levels. Several pharmaceutical companies have aldose reductase inhibitors in various stages of development and testing.

In addition to following up these prevention studies, NEI investigators have begun intervention studies in both dogs and rats. We hope that these studies will help determine the best time to begin treatment in humans and will also provide comparison points for clinical trials of different aldose reductase inhibitors.

Although these laboratory studies hold great promise for the eventual prevention of diabetic retinopathy, we must still be concerned with helping people who already have advanced stages of the disease. When people with diabetic retinopathy fail to respond to laser treatment to seal, or photocoagulate, the proliferating weak blood vessels, and an intraocular hemorrhage occurs, a vitrectomy may be performed. Vitrectomy is the surgical removal and replacement of the vitreous, the normally clear gel that fills the center of the eye. The conventional therapeutic approach has been to delay vitrectomy for a year to see if the body reabsorbs the hemorrhaged material.

The NEI has been supporting a clinical trial to investigate whether vitrectomy performed early might be of greater benefit than delayed surgery for two groups of patients: those who already have severe visual loss from hemorrhage and those who still have useful vision but a poor prognosis for hemorrhage or retinal detachment.

In 1985, investigators reported results from the trial's first group, those who had already suffered severe visual loss. They found that recovery of good vision was 10 percent higher in patients who had early vitrectomy compared to those who had delayed vitrectomy. Last October, even better results were reported with early vitrectomy in the second group of patients. Sixteen percent more of these patients retained their good vision than did those who had delayed vitrectomy.

Before concluding, I would like to tell you about a new program that will respond to our Congressional directive to increase public and professional education activities relevant to the prevention of blindness. During the past year we took steps to launch a National Eye Health Education Program, whose purpose is to make Americans better aware of how they can take advantage of research advances to prevent blindness. We recently held a national planning conference for the new program involving representatives of eye care professions, voluntary health organizations, industry, and other public and private organizations with an interest in eye care. The purpose of the conference was to identify education needs and priorities in health education and applied research in glaucoma and diabetic retinopathy, the two diseases that will be addressed first by this new program. I look forward to keeping this committee informed about the progress of this exciting and challenging new activity.

Mr. Chairman, the FY 1990 budget request for the National Eye Institute is $233,777,000. I will be happy to answer any questions.

PRESBYOPIA

Senator HARKIN. Thank you very much; 3.2, or a 3 percent increase. What is it that I have been reading so much about lately that, when you turn 40 years old you have to wear these things like you and I are wearing now, that everybody has it? I see perfectly.

The problem is, I used to be a pilot and I had good vision, but by the time I turned about age 43—it hit me at about age 43, 44, 45 and from this day I cannot read without these glasses on, but I can see everything else perfectly fine. What is that called?

Dr. KUPFER. It is called presbyopia. It is the inability to read close up without spectacles and, unfortunately, it does affect all of us. It is easily corrected with spectacles, but we are beginning to turn our attention to this condition because it is so very widespread, affecting everyone over the age of 40, as you pointed out.

Senator HARKIN. Not everyone.

Dr. KUPFER. It does affect everyone, but to different degrees. A nearsighted individual may need only take off his or her glasses to

be able to read. However, very often the individual will not do that but elect to have bifocals or some other optical correction instead.

Senator HARKIN. Does it affect men more than women?

Dr. KUPFER. No, sir; it affects both sexes equally.

Senator HARKIN. It has not affected my wife. I keep waiting for it to happen, but it has not happened yet. That is why I was wondering. It does not affect everyone. Is there any research into this as to why this is caused? I mean, it affects so many people. It is not life-threatening or anything like that, obviously.

Dr. KUPFER. We do know why this happens but we do not know by what mechanism. The "why" refers to the fact that the lens, which can easily change its shape in the young eye, loses much of the ability in aging and, therefore, cannot assume the more spherical shape necessary for reading and other close work. This ability is lost around age 40 to 45.

ULTRAVIOLET RADIATIONS AND CATARACTS

Senator HARKIN. I have been reading a lot lately about glaucoma and cataracts, new methods for treating them—lasers and other things like that, two of the most common causes of blindness or impaired vision.

I understand we still do not know precisely what triggers these diseases. I understand that one promising theory is that steroid hormones like cortisone and damage from sunlight might trigger both diseases. Can you tell us about any new information about the underlying causes of glaucoma and cataracts and what is being done in this area?

Dr. KUPFER. These are two areas in which very intensive research has been conducted. I will speak of cataract first. One hypothesis is that exposure to high levels of sunlight over many years may be a risk factor in the development of cataract. To test this hypothesis we supported a study that was conducted in Lhasa, Tibet, which at an elevation of about 4,300 meters receives a very high level of ultraviolet radiation during the daylight hours.

It turns out that, despite the fact that Lhasa receives this very high level of ultraviolet radiation, there is only about a 60 percent increase in the prevalence of cataract among its inhabitants as compared to an equivalent setting in Beijing, China.

We expected a much larger effect from such a high level of ultraviolet radiation. Therefore it has now become more clear that there are many factors that contribute to the development of cataract, that these factors can be cumulative, and that ultraviolet radiation may play a role in this spectrum. But there are still unanswered questions that are being very aggressively pursued.

STEROID TREATMENT FOR GLAUCOMA

Senator HARKIN. For glaucoma?

Dr. KUPFER. In the area of glaucoma, we do not know the mechanism of development of increased pressure in the eye. We do know, as you pointed out, that steroids will cause a very high elevation of interocular pressure in certain individuals. But we still do not know the mechanism underlying this phenomenon, and therefore, our research efforts need to continue.

Similarly, cataracts have been related to topical or systemic use of steroids and the mechanism of this process is also being actively investigated.

LASER SURGERY FOR THE TREATMENT OF MYOPIA

Senator HARKIN. How close are we to using laser surgery to correct the nearsightedness, farsightedness, and astigmatism—an article that was in the New York Times late last year about what they are doing to correct the curvature of the eye, the cornea. How close are we to something like that?

Dr. KUPFER. The intent of this procedure, Senator, is to change the curvature of the cornea and the refractive characteristics of the eye thereby correcting the myopia.

There is quite a bit of work going on, but a limiting factor to reaching a successful correction is the lack of basic knowledge about how the cornea, the front part of the eye, responds to laser treatment.

To address this problem we have planned two workshops, one will be held in September, the other in February, to bring together researchers who can provide basic information on the physical, chemical, and biologic properties of the cornea. With this knowledge we can better understand how the cornea responds to and, therefore, how to better use the laser.

I would say we are at least 5 to 10 years away from having a successful procedure. It will take us that length of time to lay the foundation to understand better how the cornea can react to this type of procedure.

NEW EYE CHART FOR MEASURING VISUAL ACUITY

Senator HARKIN. What about this new eye chart that replaces the traditional eye chart? The new chart reveals a dimension of vision called contrast sensitivity and I understand that the National Eye Institute sponsored trials in it.

Dr. KUPFER. Yes, sir; this is a very recent development. As you know, the traditional eye chart that we are all familiar with measures our ability to see letters that become smaller and smaller. This measures our ability to see at a smaller visual angle.

The new chart has letters of the same size, but the contrast between the letter and its background decreases. Therefore, we are measuring a different property of the eye. And it turns out that this property of the eye is much more sensitive to changes in the function of the retina than the traditional visual acuity measurement. Previously, an individual may have had a visual acuity that we assume is normal—20/20—but he or she still may have had a defect in contrast sensitivity. This chart is also being used to study changes in the eye from optic neuritis, a condition that often occurs in patients with multiple sclerosis. Although the vision of these patients, after recovery may be measured as 20/20, they complain of not being able to see as well as they used to. We can now document this effect as a change in contrast sensitivity. So this new eye chart is a much more sensitive way to measure the function of the retina.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you all very much for excellent testimony. We appreciate it very much.

We will submit some additional questions for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

BLINDNESS: MOST FEARED HANDICAP

Question. Dr. Kupfer, as you know, a recently completed Gallup survey found that blindness is the most feared disability or handicap, and the same survey found blindness ranked fourth after AIDS, cancer and Alzheimer's Disease as "the worst disease or ailment."

Glaucoma and cataracts are two of the most common causes of blindness or impaired vision, yet we still do not know precisely what triggers these diseases.

I understand that one promising theory is that steroid hormones like cortisone and damage from the sunlight may trigger both diseases.

What can you tell us about the underlying causes of glaucoma and cataracts?

Answer. It is known that topical or systemic use of steroids such as glucocorticoids may induce elevated intraocular pressure in susceptible individuals. Studies have shown that there are molecules in the eye which bind glucocorticoids, and this finding has led scientists to think that there may be a link between the binding of this type of steroid hormone and the rise in intraocular pressure that is the hallmark of glaucoma.

And, indeed, studies indicate that steroids may play a role in the normal physiology of fluid drainage from the eye. When fluid does not drain properly from the eye there is a rise in pressure within the eye which leads to damage to the optic nerve, decreasing its ability to carry visual information to the brain.

Recent studies have shown that when steroids bind to receptor molecules on the surface of cells in the eye, compounds called prostaglandins are synthesized. Prostaglandins affect the cells that control fluid flow. Additional investigations have shown that when steroids are applied to human cells grown in culture the genetic function of the cells change.

By employing the techniques of molecular biology to identify and characterize the effects of steroids on the cells of the eye involved in control of fluid drainage, scientists hope to gain a better understanding of the cause of glaucoma.

Cataract is a clouding of the normally clear lens of the eye and is commonly associated with advancing age. In addition to aging, cataract may occur as a consequence of diabetes or other metabolic disorders, after exposure to toxic environmental agents such as radiation and light, or may be an inherited or congenital disease.

During the past ten years a great deal of information has been obtained on the biology of cataract formation. Advances in

our understanding of cataract have come from basic laboratory research applying the techniques of molecular biology, such as recombinant DNA and gene splicing, to elucidate the factors underlying normal lens transparency and the mechanisms of cataract formation.

Evidence indicates that both molecular oxygen and other highly reactive forms of oxygen are involved in oxidation of lens proteins and that this oxidation is a critical factor in the development of age-related cataract. Current research is aimed at identifying components of the lens that are susceptible to oxidative damage and then finding a way to block the oxidation of those components. One of the lens components that may be susceptible to oxidation is a molecule which is involved in salt and water balance within the lens. Other functionally important molecules may similarly be susceptible to oxidative damage and, therefore, become altered in function, leading to cataract formation.

The human lens is normally exposed to various forms of radiant energy, including natural sunlight. Although sun-light has not been proven to be the sole cause of cataract, current evidence indicates that ionizing radiation and ultraviolet radiation may play a role in the production of some types of cataract. There appears to be a linkage between light-induced oxidation of the lens amino acid, tryptophan, and the production of a pigmented material seen in a type of cataract called brunescent cataract.

LASER SURGERY: NO NEED FOR EYEGLASSES

Question. I understand that doctors are testing dramatic new laser surgery that they hope will correct vision problems and eliminate the need for eyeglasses.

The procedure takes only 30 to 60 seconds and according to Dr. McDonald, an ophthalmologist at the Louisiana State University Medical School in New Orleans: "It could revolutionize eye care" and "has the potential for an instantaneous solution."

Dr. Kupfer, how close are we to using laser surgery to correct for nearsightedness, farsightedness and astigmatism?

Answer. There are a number of new surgical techniques being developed to correct refractive errors. Among these is the use of an excimer laser that is capable of vaporizing one layer of corneal cells at a time, thus making very precise shaping of the cornea possible. At the present time this technology is undergoing experimental investigation in animals, with only very preliminary pilot studies in humans.

Before we can use the laser on a practical clinical basis we must have a much better understanding of how the laser energy interacts with corneal tissues. We want to be very certain that all biosafety issues have been resolved before we proceed with human applications. To this end, we are sponsoring two workshops during the next year that will focus on the physical,

chemical, and biologic properties of the cornea. It will probably take at least five to ten years to lay the scientific foundation necessary to adequately evaluate the safety and clinical effectiveness of laser refractive surgery.

TIGHTER BLOOD SUGAR MONITORING MAY HELP PREVENT OR DELAY VISION LOSS.

Question. Retinopathy is an eye disease that affects the blood vessels of the retina, and diabetic retinopathy has become a leading cause of visual impairment and blindness in Americans over twenty years of age.

I understand that a ten-year study of diabetics in Wisconsin which followed 1,878 patients showed that tighter blood sugar control delays visual impairment among diabetics.

Is that correct?

Answer. The study you refer to was conducted among 1,878 diabetic patients who had a baseline examination (1980-1982) and a follow-up examination four years later (1984-1986). Poor blood sugar control, as measured by a baseline glycosylated hemoglobin, was found to be a strong, independent predictor for the development of retinopathy and progression of severity or progression to proliferative diabetic retinopathy over the four-year period. This finding was true for the 891 patients classified as younger-onset diabetics (diagnosed before age 30 and treated with insulin) and the 987 older-onset diabetics (diagnosed at or after age 30 either taking or not taking insulin). This finding suggests the potential public health importance of maintaining good blood glucose control. Modest improvements in blood glucose control reduced the risk for development of proliferative retinopathy, which can lead to visual impairment and blindness. The National Eye Institute is funding the continuation of this study to determine the ten-year incidence and progression of diabetic retinopathy, macular edema, and visual impairment.

Question. Can we assume that tighter blood sugar control among diabetics will also delay or eliminate other complications caused by diabetes?

Answer. There is reason to believe that better metabolic control of blood glucose may reduce the other complications of diabetes and, possibly, prevent some of the microvascular and macrovascular damages of the disease. This question is being addressed directly in the Diabetes Control and Complications Trial sponsored by the NIDDK.

NEW EYE CHART PROMISES EARLIER DETECTION OF EYE DISEASES

Question. I understand that a new eye chart when used with the traditional eye chart promises a more effective method of screening for eye disease than existing methods.

Apparently the new chart reveals a dimension of vision called "contrast sensitivity" which is not measured by

traditional charts but is associated with several types of eye disease.

What can you tell us about these new eye charts?

Answer. The traditional eye charts used to measure visual acuity assess the ability to see and recognize high contrast test objects (letters) of increasingly smaller size. Although this type of measurement provides an accurate assessment of vision in patients with refractive disorders and certain ocular conditions, it often does not provide an accurate assessment of vision in patients with optic nerve disorders or some retinal abnormalities. Patients with resolved optic neuritis or multiple sclerosis may show normal visual acuity but still complain of poor vision. Testing under conditions of low contrast can reveal the nature of this residual deficit.

Charts that measure contrast sensitivity present objects or letters of fairly large size, but the contrast between the objects and the background decreases with successive lines on the chart. One form of these charts uses letters like those on the traditional visual acuity charts so the patients are already familiar with the format.

This test of contrast sensitivity is currently being used as an outcome measure in two NEI-supported clinical trials: the Optic Neuritis Treatment Trial and the Macular Photocoagulation Study. It is hoped that use of these new charts will provide additional information on the effectiveness of the treatments evaluated in these two trials.

Question. Should they be used by all doctors for routine eye exams?

Answer. For most purposes, the commonly used visual acuity tests are sufficient for detecting reduced visual function. If, however, visual acuity appears normal but the patient still complains of poor vision, it would probably be worthwhile to include contrast sensitivity and other tests of visual function to explore further the reasons for the reported problem.

NATIONAL EYE HEALTH EDUCATION PROGRAM

Question. This committee directed the National Eye Institute to launch an education program to motivate the public and health professionals to be more alert to the sight-saving potential of early detection.

I understand that this past March you held a national conference to help set priorities for this effort.

Please describe for the committee the National Eye Health Education Program you have developed.

Answer. The initial focus of what the National Eye Institute (NEI) has designated as the National Eye Health

Education Program (NEHEP) will be public and professional education relating to the importance of early detection and treatment of glaucoma and diabetic retinopathy. In the future, other topics, such as coping with low vision, may be added to the program.

We plan to develop the NEHEP as a broadly based and distinctive program that takes advantage of lessons learned from other successful NIH-sponsored health education programs. One of the chief lessons learned from these programs is the importance of involving intermediary organizations in the public and private sectors in the development and execution of a coordinated, sustained, multimedia national health education program. We intend for the NEI to coordinate the development of strategies, messages, and materials for the national program and, based upon these, for the participating organizations to carry out activities that will be further defined and shaped by their own missions and resources.

Part of the initial implementation of the NEHEP was the organization of a Program Planning Conference, held March 2-3, 1989, in Baltimore, Maryland. Conference invitees included more than 65 representatives of organizations, including those of the eye care professions, voluntary health organizations with an interest in eye care, eye care industry representatives, and other public and private sector groups and individuals.

The outcome of the meeting was a set of recommendations made by the conference participants to the NEI for development of the NEHEP. These include preparing a planning conference summary report; establishing a coordinating committee to help guide the program's future projects; preparing a strategic plan specifying program activities and roles for intermediary organizations; sponsoring a national survey to measure the public's knowledge, attitudes, and practices regarding glaucoma and diabetic retinopathy; cataloging eye health education materials and programs currently available; developing new materials and programs, including mass media components; and setting up a toll-free telephone number for eye health information. We are now in the process of implementing these recommendations.

LOW VISION ENHANCEMENT WITH SPACE AGE TECHNOLOGY

Question. I understand that the Wilmer Eye Institute at Johns Hopkins University is developing, in collaboration with NASA, glasses that essentially are TV screens to help people with severely impaired vision or low vision see more perfectly.

When will this technology be available for general use?

Answer. The device in question is intended to take in a visual scene or printed materials via miniature TV cameras and, through real-time computer image processing, present that information in an altered form that a visually impaired person could use. The image might be magnified or systematically distorted in a way that is compatible with the individual's remaining visual capabilities. It is being developed in stages,

with research proceeding along several lines simultaneously at both Hopkins and NASA.

Glasses, incorporated in a head mounted display, are currently undergoing laboratory evaluation at the Wilmer Eye Institute. This portable reading package should be available as a commercial prototype in two years.

NASA is developing the non-image processing hardware that will ultimately be integrated with the head mounted display. That equipment should be available for laboratory study at Wilmer in 12-18 months. Then it may take several years to develop the computer algorithms that will drive the image acquisition and processing functions of the device. These improvements will be added to the head mounted display as they become available so a fully functional unit is expected to be available in about five years.

DISEASES AND BLINDNESS

Question. In your testimony before this committee last year, you indicated that Americans spend roughly $16 billion annually on diseases that affect the eye and blindness. You stated further that your Institute supports about 70 percent of all vision research in this country. Could you tell us who supports the remaining 30 percent? To what extent is the private sector involved in vision research to combat blindness?

Answer. In addition to the National Eye Institute, financial and non-financial support for vision research is provided by other agencies of the Federal Government, including other institutes at the NIH and the Department of Health and Human Services; local and state governments; and a variety of private, philanthropic, and voluntary health organizations. In particular, in recent years the pharmaceutical industry has increased its support of basic and clinical research related to eye and vision disorders.

The contribution to vision research that is made by private organizations cannot be measured by dollars alone. Besides giving financial support to promising young investigators, these organizations are often able to provide funding for facilities construction, equipment, and other vital research resources that cannot always be obtained from public funding organizations. They also frequently provide timely funding for the development of innovative techniques or for exploiting unusual opportunities that may otherwise have been lost in the course of the necessarily longer review process required for government research grant applications.

INVESTIGATIONAL DRUG STUDIES

Question. Could you give us the status of your investigational drug studies involving the following drugs or combinations of:

a. Ganciclovir (has shown some potential antiviral activity against cytomegalovirus retinitis)

b. Foscarnet (has shown some activity against HIV and herpes viruses)

c. AZT (currently in clinical trials, in combination with other drugs, for possible treatment of the AIDS virus)

Answer. The FDA's Anti-Infective Drugs Advisory Committee has recently recommended approval of Syntex's Cytovene (ganciclovir) for treatment of cytomegalovirus (CMV) retinitis in AIDS patients provided several Phase IV studies are conducted.

NEI intramural scientists are collaborating with NIAID investigators on a randomized controlled clinical trial of foscarnet in the treatment of CMV retinitis in patients who are currently receiving AZT and patients who are not receiving this drug. These scientists hope to determine whether foscarnet can delay significantly the progression of CMV retinitis and whether it can be used safely in combination with AZT. This trial was begun in November 1988 and is still recruiting patients.

AIDS AND OPHTHALMIC DISORDERS

Question. With the incidence of AIDS increasing in certain subpopulations, and the association of certain ophthalmic disorders with AIDS, have you seen or are you seeing a corresponding increase in those ophthalmic disorders and subpopulations that are associated with AIDS?

Answer. In general, there has been a parallel increase between the number of AIDS cases and the number of individuals with ophthalmic disorders associated with AIDS. Approximately 65 percent of AIDS patients eventually show some ocular involvement. It also should be noted that additional ocular manifestations of AIDS are still being described. For example, clinical scientists at the NEI have described two ocular complications of AIDS that had not previously been described. One is a new form of bacterial retinitis that is extremely damaging to the eye but responds more readily to treatment than do viral infections. The other is a large retinal vein occlusion that is similar in appearance to Eale's disease, a retinal vascular disease seen in young adults.

Question. In light of the fact that certain ophthalmic disorders, along with the associated AIDS problem, occur disproportionately in minorities, could you tell us how many grants have been awarded to minority institutions? Could you please identify those institutions, and are there any plans to increase support to more minority institutions for medical research? If not, why not?

Answer. The NEI is currently recruiting clinical centers to participate in a treatment trial for cytomegalovirus retinitis. It is expected that these centers will have study populations representative of persons affected by the AIDS epidemic and should include minorities and persons referred from minority institutions.

At present, no NEI research grants have been awarded to minority institutions to study AIDS or its associated ophthalmic disorders. However, in 1989, NEI has seven research grants that deal with non-AIDS basic vision research projects at six minority institutions.

MINORITY BIOMEDICAL SUPPORT

Question. We note that in your budget request you have allotted $288,000 for 1989 and $298,000 for 1990 "minority biomedical support". Could you please define what this really means? (Is this for summer student experience, principal investigators, etc).

Answer. These budget requests represent the expected amounts of money needed to co-fund appropriate vision-related research projects through the Minority Biomedical Research Support applications presented to the Division of Research Resources. This support may take the form of salary for the principal investigator and support staff, laboratory supplies and/or stipends for undergraduate and graduate students, and funds for student travel expenses.

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID F. RALL, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Our next panel will include the National Institute of Environmental Health Sciences, Institute on Aging, Arthritis, Research Resources, Nursing Research, and the Fogarty International Center.

I would like to start first with Dr. Rall for the National Institute of Environmental Health Sciences. The fiscal year 1990 budget for this is $230.8 million, 3 percent increase over 1989. Dr. Rall, welcome to the subcommittee, and please summarize your statement for us.

Dr. RALL. Thank you very much, Mr. Chairman. I am very pleased to be here today and to discuss a few of the NIEHS research results which have major impacts on public health.

For many years our NIEHS scientists have been studying air pollution, including ozone and some key greenhouse gases. High in the atmosphere ozone blocks the sunlight associated with skin cancer, and now I should say perhaps cataracts and an altered immune response.

Down where we live ozone is linked to lung damage. NIEHS studies on ozone and other common pollutants, sulfur oxides, particulates, nitrousoxides, and carbon monoxide are examples of how NIEHS produces the information needed to develop standards for air pollutants. In fact, most of the information the health regulator agencies use is derived from studies supported by NIEHS. I should emphasize, however, that NIEHS is not a regulatory agency, but only performs research and provides information.

Our studies on an old problem, lead, continue to produce new information. Houses with lead paint and lead in water supplies are the major sources of lead exposure for children today. Some five to six million houses have lead paint which threatens an estimated two million young children. The evidence for the danger from exposure to low levels of lead, especially in our youngest, continues to mount. NIEHS supported scientists are looking for effective, safe preventions/treatments to lower body lead burdens in searching for ways to reduce and prevent exposure.

The Washington Post Tuesday Health Magazine a few weeks ago reported comprehensive studies of lead based in part on a symposium we held in conjunction with the National Institute of Child Health and Human Development, and I think it is a very readable and comprehensive and worth a few minutes to peruse.

With this committee's support, NIEHS has initiated studies to further understand the lung cancer risk from lifetime residential

exposure to radon. We will study over 4,000 nonsmokers and smokers from Connecticut, Utah, and Southern Idaho.

The NIEHS NTP chemical testing program has included dichlorvos used in pest strips, ochratoxin-A found in corn, peanuts, stored grains, meats, and so forth, and bromoethane, a chemical intermediate and octane booster. All of these chemicals showed evidence of carcinogenicity in experimental animals.

It is worth noting that while many claims are made that all chemicals cause cancer, the NIEHS NTP has compiled an impressive list of chemicals that do not, including a red dye rhodamine 6G, one of industry's most common solvents, toluene; the antibiotics tetracycline, erethromycin, and ampicillin, ascorbic acid; malathion, and important to some people, the yellow in pencil paint as well as menthol and others.

One research example that I think is very exciting comes from our superfund basic research program where scientists are using the white rot fungus which can rot wood and make onions mushy, to break down and detoxify a variety of environmental pollutants, including the PCB's, dioxins, coal tar, DDT, dieldrin, and others. These scientists want to learn how the fungus breaks down these environmental toxins and then use the strains of white rot fungus that do the best job in detoxifying chemicals to become effective, economical, biological, hazardous waste treatment systems.

PREPARED STATEMENT

Mr. Chairman, the budget for NIEHS is $226,471,000 without AIDS, an increase of about 3 percent. I would be delighted to answer your questions. Thank you.

[The statement follows:]

STATEMENT OF DR. DAVID F. RALL

The National Institute of Environmental Health Sciences (NIEHS) leads the nation in basic research into the effects of environmental agents on human health. Information developed in NIEHS programs is shared with the broader scientific, medical, governmental, and general public communities where the findings are used to protect human health from harmful environmental agents.

In 1988, reports of dying wildlife in poisoned reservoirs and estuaries sewage washing ashore on popular beaches, contaminated drinking water from agricultural fields, toxic dumps and industrial site runoff, and grim and fanciful descriptions of what life on a "greenhouse" Earth may become, raised the world's awareness of the environment. The reports reinforced the need to answer complex questions about the environment and human health, questions that demand an adequate science base to produce valid answers.

I wish there were time to share with you the excitement we in environmental health sciences feel about the developments that are taking place in our field, as well as the sense of responsibility we have to apply these developments to the environmental health challenges facing us.

Today I would like to share with you some of our work on ozone, a public health concern in two different settings; an update of our studies of lead; emerging information on oncogenes; and research into the effects of radon exposure in homes. In addition, NIEHS scientists are reporting exciting new findings from our studies in reproductive epidemiology, including a new approach to detecting previously unrecognized early pregnancy loss; and one of our Superfund grantees is investigating a fungus, long known for its thorough and inexorable breakdown of wood into carbon dioxide and water, that may open the way to safely detoxifying some of the most intractable contaminants in Superfund sites.

NIEHS scientists have studied air pollutants, including ozone and some key greenhouse gases, for years. Their research is in the forefront of studies that will identify emerging environmental public health concerns that may arise as some of the minor pollutant gases associated with the greenhouse effect become more important.

Ozone is a public health concern with two faces. Ozone in the upper atmosphere blocks skin cancer-causing ultraviolet light from the sun. Increases in ultraviolet sunlight also contribute to cataracts and to alterations in the immune system. NIEHS-supported scientists are looking at how ultraviolet radiation damages DNA, the hereditary map, and how skin cells repair that damage. Understanding the mechanism of injury could help in finding ways to block ultraviolet damage, and in finding ways to repair the injuries.

There is evidence that some stratospheric ozone is being destroyed by chlorinated compounds that escape from human activities. These destructive compounds include chlorofluorocarbons (CFCs) used as coolant gases and plastic foaming agents. If society stops using CFCs, we must ask what are the human health consequences of proposed replacements, a question the NIEHS scientists can help answer. NIEHS studies of chloroethane and bromoethane, two potential replacements for CFCs, indicated the compounds cause cancer in animal models. The

findings suggest more information on health effects is needed before those compounds are widely used.

Ozone at ground level, produced when gasoline vapors and emissions from burning fossil fuel interact with sunlight, is associated with effects on lung function ranging from asthma attacks to increased risk of respiratory illness. NIEHS studies with exercising adults and healthy children found decreased lung function as ozone and related air pollutants increased, though the ozone levels were within existing ambient air quality standards. These effects of ozone were greater in pollutant mixtures than could be explained by simply adding the individual effects seen in laboratory studies of the pollutants.

NIEHS scientists have designed laboratory studies to expose rodents to ozone at the concentrations and for the periods of time experienced by 115 million people in this country every year. The low dose ozone exposure in the study, 0.12 parts per million (ppm), is the level measured in Los Angeles some 85 out of 95 days during the summer. The mid-level exposure of 0.5 ppm occurs four or five times during a Los Angeles summer, and is known to affect the lung. The highest exposure for the study, 1.0 part per million, might occur if ozone were released accidentally, as from a water treatment plant purifying water with ozone.

Ozone as a co-carcinogen will be studied using a cancer-causing ingredient in tobacco smoke familiar to NIEHS investigators, NNK. NIEHS scientists' well developed understanding of the nitrosamine in tobacco smoke, known as NNK, will make it easier to identify responses to the combined exposure that are related to ozone.

Houses with lead paint and lead in water supply systems are today's leading sources of lead exposure for children. Some 5 to 6 million deteriorating units among the nation's 41 million lead-painted housing units have lead-shedding problems to the extent that they could be called "toxic houses." These toxic houses threaten an estimated 1.8 to 2 million young children at the same time evidence of the harmful consequences of exposure to low levels of lead for young children and the fetus--by way of maternal exposure--continues to mount. NIEHS-supported scientists are actively pursuing questions of effective, safe treatment to lower body lead burdens from lead exposures, and they are looking from safe and effective ways to lessen the potential for exposure.

Exposure of the fetus through mobilization of maternal bone lead, producing a second generation victim, is one of the newest questions to be raised. These sources of exposure are a formidable prevention challenge for researchers and the public health community. These complex issues also challenge pediatricians and obstetricians faced with advising patients whose blood lead concentrations may now be of concern because of growing understanding of low-level exposure effects.

NIEHS scientists are studying how the adverse effects of lead persist, and the implications of that persistence for the individual and society. The insights and methods they have developed with lead are being used in other studies. For example, the test for postural sway developed by our grantees to detect effects of low level lead exposure on motor function in children is being evaluated for measuring workplace exposure effects in adults. NIEHS scientists have begun to explore the effects of lead in aging populations. They are looking at increased susceptibility to lead's effects as metabolism changes and the lead stored in bone is released, particularly for postmenopausal women with osteoporosis.

NIEHS studies of the mechanisms by which chemicals induce tumors, as compared to the nature of spontaneous tumor development, are being done, in part, in cooperation with private sector scientists. These studies could increase our ability to determine which chemicals pose a significant risk of causing human cancer.

NIEHS scientists are developing and using sensitive tests to detect activated oncogenes. They have detected a much higher percentage, 85 percent, of activated oncogenes in human lung tumors than previously reported. They found the K-ras oncogene in 30 to 40 percent of human lung adenocarcinomas, which agreed with earlier reports. In addition, they have detected other, as yet unidentified, oncogenes in human lung tumors, without the K-ras oncogene. The K-ras is a target in chemically-induced rodent lung tumors. These findings could be important to developing treatments and preventing this human cancer.

NIEHS scientists are working with colleagues at the National Institutes of Health to develop a mouse strain with foreign genetic material that will give the model special susceptibility to tumor formation. This mouse model may speed the identification of cancer-causing chemicals, taking months instead of years, and aid in solving the problem of identifying chemicals which cause cancer but are not mutagenic in existing short-term tests.

NIEHS scientists are studying tumor suppressor genes which turn off tumor cell growth. When this gene is inactive or missing, cancer can develop. The scientists postulate that loss of this gene may play a role in the long latency period associated with some environmental cancers.

Research with more than 4,000 adults will examine lung cancer risk from lifetime residential exposure to radon. Residential radon exposure has been receiving widespread attention. Most of our existing information about radon comes from studies of miners with extremely high radon exposures. In addition to involving exposures much higher than those found in the home, studies of miners tend to be limited to healthy males.

In collaborative studies, 1,850 nonsmokers and 2,300 smokers from Connecticut, Utah and southern Idaho will participate in a study which will look at the interaction between radon and smoke exposure in altering lung cancer risk. As part of the study, radon levels will be measured in all past and current residences of the participants and information on other lung cancer risk factors will be gathered. In addition, a pilot effort involving 375 children in Connecticut will explore a possible radon and childhood cancer link.

NIEHS scientists are testing a number of the chemicals leaking from domestic and industrial waste dumps, as well as substances we encounter in our daily lives. Their studies have confirmed some suspicions about health hazards, such as the past strip ingredient dichlorvos; the fungal ochratoxin A-- found in corn, peanuts, storage grains, cottonseed, meats, dried fish, and nuts; and bromoethane, used as a chemical intermediate in making pharmaceuticals, and in boosting octane in gasoline. All show evidence of carcinogenicity in experimental models.

Over the same period, NIEHS testing has found no firm evidence of carcinogenicity in other common chemicals such as the red dye rhodamine 6G, used to color natural and synthetic fibers and as a research chemical, and the widely used solvent, toluene.

Fertility and reproduction may be among the most sensitive indicators of environmental insult. NIEHS scientists are

conducting basic research into the effects of environmental agents on the capacity to conceive, and on the development of the fetus and the young child.

In a recent project that generated much public interest, NIEHS scientists used a sensitive assay for the hormone human chorionic gonadotropin to detect early pregnancy. With this method, researchers can track pregnancy and pregnancy loss very early after conception. The study found a pregnancy loss of 31 percent of all conceptions, with 22 percent of the conceptions lost before the woman was aware that she was pregnant. The methods developed are being used to study pregnancy loss in the microelectronics industry and are to be used in studies of California drinking water, video display terminal users, and female lead workers in China.

Exciting possibilities are emerging from one of the newest NIEHS efforts, the Superfund Basic Research Program. In one group of projects, scientists are examining the potential of the white rot fungus for breaking down a wide variety of environmental pollutants including PCB, dioxin, coal tar, DDT, dieldrin, and others.

These scientists know that the family of fungi does its best work when it's starved. They want to learn how the wood-rotting fungus breaks down environmental toxins, and then use the fungi in biological hazardous waste treatment systems that are effective and economical. The NIEHS grantees plan to select the strains of white rot fungi that have the best capabilities and highest capacities for detoxifying the chemicals.

Mr. Chairman, the budget request for the National Institute of Environmental Health Sciences is $226,471,000. I would be pleased to answer any questions you may have.

TOLUENE

Senator HARKIN. Thank you very much. You said that you absolutely rule out toluene as a carcinogen?

Dr. RALL. Toluene. It is a very common industrial solvent.

Senator HARKIN. It is something different than I am thinking of. Is that a petroleum distillate?

Dr. RALL. Not really. It is a synthetic chemical. I think you are thinking of something else.

Senator HARKIN. I am thinking of something else. Dr. Rall, you know there is a great concern in rural and farm areas as to health effects of agricultural chemicals. I have heard reports in Iowa of very high cancer rates in certain areas with popular concern being that they are being caused, at least to some extent, by agricultural chemicals.

I know you are conducting research on the health effects of agricultural chemicals. Could you tell the committee what you are doing in this area?

Dr. RALL. I would be delighted to. We are concerned about the problem of the environment as it effects the farm and the agricultural worker. We are studying a good percentage of the pesticides that farmers use, and previous studies have been conducted with ethylenedibromide, the phenoxy herbicide such as 2-4D and 2-4-5T, 2-3 dichloropropylene, trichlorifon, lindane, pentachlorobenzene, and most recently dichlorvos.

It is EPA's responsibility under FIFRA to insure that the manufacturers test their chemicals. As we have seen with Alar, this can be a very long and drawn out process. That Alar was a potential problem was clear in the early 1980's, and if effective and prompt testing had begun at that time, the great Alar apple scare could have been obviated, suggesting the sooner you test a compound and the better you test it, the better it is for everybody concerned.

Farmers are not only exposed to pesticides. Many of the commercial solvents, the compounds with which they clean their tractors and so forth are also dangerous. The cellosolves are an interesting group of ethoxy alcohols. The cellosolves that you can go down in the hardware store and buy today has not been adequately tested for chronic toxicity. We are embarking on a program to test that.

Ground water contamination is always a problem with the various halogenated hydrocarbons, nitrites, nitrates, pesticides, and so forth, and we are deeply involved in that. Getting such information to the public is always a problem. We have three vehicles by which we perform that. First are the technical reports of our toxicity studies. These technical reports are made widely available and certainly to the universities and university libraries. The technical report summary is written in a comprehensible fashion even if the rest of the article is strictly technical.

Second, we put out a journal, Environmental Health Perspectives, which tries to look broadly at issues of environmental health and we have had issues on new or nontoxic pesticides and so forth. This, I think, has been very useful.

Finally, we publish the annual report on carcinogens which describes in lay language those chemicals for which there is adequate evidence that they either are human carcinogens, or may reasonably be expected to be human carcinogens. I must admit there is some question as to whether the next issue will be published because some companies feel we are unfairly treating their chemicals.

One other area that we are very interested in is combination studies, the toxicity of combinations, because we know we are not exposed to a pesticide alone or only to a water pollutant and so forth. We have developed a number of interesting ways of looking at toxicity of combinations of chemicals and we think we will be successful.

Overall our program is well over $15 million in agricultural chemicals.

Senator HARKIN. Do you have any research centers that focus on agricultural chemicals?

Dr. RALL. No; we do not. We have a center at Corvallis, OR, that does not focus primarily on agricultural chemicals but is certainly more agriculturally oriented than the rest of those which tend to be in metropolitan areas.

Senator HARKIN. It seems to me with all of the chemicals used in agriculture and because of the high level of public concern about it, witness the Alar story, and because it has been proven in the past that some of our pesticides have been highly carcinogenic, DDT for example, and because the Environmental Protection Agency has not gone back to reclassify those—I don't know how many we have--several thousand that they have not reclassified yet.

Dr. RALL. That is right.

Senator HARKIN. They just have not been able to do it. I am wondering if it would be wise to have a center to be focused, just narrowly focused, on agricultural chemicals.

Dr. RALL. I think it is a good idea. I think it does not have to be narrow. I think it can be very broad.

Senator HARKIN. Things that go on crops and on the land and get in water runoff, that get in the food that we eat, that kind of thing. I said narrow only because of the area rather than getting into everything else. More and more people are very concerned about what they are eating out there. There is more and more of a market for certified foods grown without pesticides and herbicides. What can you do? There is nothing you can do about it.

People are getting concerned about it. That is why I think a research center to either allay those fears and let us know which chemicals are fine and good and those that are not so we have some basis of knowledge on this.

Dr. RALL. I agree. I think such a center would be very useful for the consumer, too, because, as you say, you would learn more about those chemicals.

Senator HARKIN. This is something that just came out when I was out at the Institute. Your Institute actually is located in North Carolina?

Dr. RALL. That is right. If I disappear before the end of this total session, it is because I have to catch a plane.

Senator HARKIN. And then you have another one in Arizona. What is that?

Dr. RALL. The Arthritis Institute has a small——

Senator HARKIN. That is part of the National Institute of DDK.

Dr. RALL. DDK.

Senator HARKIN. Can you operate in North Carolina?

Dr. RALL. I do very well. I am not sure what Dr. Wyngaarden——

Senator HARKIN. I mean to operate that far away from the Institute itself.

Dr. RALL. It is an indirect subsidy of the local airlines. It works very well. There are three marvelous universities, one of which will have the opportunity to have the new professor in a few months, in the immediate area. The scientists at NIEHS have a very close relationship with these universities. We have a lot more graduate students than big NIH and so forth. It is delightful. Two or three of us have to travel more than we would like. That is about the major disadvantage.

Senator HARKIN. I was just wondering about the location of institutes off-campus, now they operate that way and whether that might be advisable or not advisable for other institutes.

Dr. RALL. The problem for our institute is that we interact so much with regulatory agencies who are all quartered here. It is perhaps more of a burden than for some institutes which would be less related to this sort of regulatory aspect of medicine.

Senator HARKIN. Last summer there was a report published in the New England Journal of Medicine that as many as one in three pregnancies end in failure. It said it was recently discovered another 22 percent of pregnancies are lost before they were detected.

Are you doing any research in this area? Why does this come under your jurisdiction?

Dr. RALL. It does not come into our jurisdiction in that sense, but one of our jobs is to develop sensitive methods to determine dysfunction in either animals or humans, and the whole reproductive process is a very delicate process and we think very susceptible to perturbation by environmental agents.

At the animal level you can detect that the first sign of many very toxic compounds is a decrease in the litter size. So working with some scientists from NIH and Columbia University, Dr. Wilcox at NIEHS developed an elegant method to determine human pregnancy very rapidly and very precisely using molecular biologically derived assay for human chorionic gonadotro. That study that he published was the baseline study. We now hope to look at populations of women exposed in factory situations or exposed to environmental agents to see if their reproductive performance is diminished.

We have an abstract out which suggests that pregnancy is delayed as a function of the amount of caffeine you ingest. The more caffeine the longer it takes a woman to become pregnant, an unexpected interesting finding, but we want to apply that to environmental health problems.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much. We will have some additional questions which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

GLOBAL WARMING

Question. We have heard a lot about global warming resulting from the release of "greenhouse" gases. In fact, I understand that we have an annual increase of 2.5 billion metric tons of CO2 released to the atmosphere each year. What are the health effects of global warming?

Answer. Global warming is a very complicated issue with many causes and a variety of potential health effects. We can assume, for example, that air quality will be poorer, certain tropical and subtropical diseases will be more prevalent, and so forth. What we do not know is whether some number of substances that are not toxic in today's environment could become toxic in a warmer world due to increased use of air conditioning, differing fuel systems, or even just because of a rise in their temperature. We can also guess that certain population groups such as the elderly will be more susceptible when the body may not function as efficiently. We hope to have a better feel for these questions after our conference on this topic in November.

MISCARRIAGES

Question. Last summer Newsweek carried a story reporting research published in the New England Journal of Medicine that as many as one in three pregnancies end in failure. While about 15 percent of all recognized pregnancies end in miscarriage, it was recently discovered another 22 percent of pregnancies are lost before they were detected. Dr. Rall, should we be concerned about this news and does it represent a new level of environmental risk that we were previously unaware of?

Answer. The discovery that 22 percent of pregnancies end in subclinical loss is an important advance in our understanding of human biology and may serve as an early indicator of environmental injury. At this time it is not known how many of these pregnancy losses are caused by environmental hazards.

Question. What research are you doing in this area?

Answer. We are providing consultation to industry and universities who are adapting our methods to their studies of specific occupational and environmental exposures. More directly, we are setting up a study in China to look at the effects of occupational lead exposure on early pregnancy loss. This next generation of studies should tell us whether very early pregnancy is a time of particular vulnerability to environmental toxins.

Furthermore, we are studying the basic cellular and molecular biology of the mouse uterus and the human uterus. These studies will provide fundamental information and, perhaps, markers for understanding the process whereby the embryo implants and is nourished early in pregnancy.

AIR POLLUTANTS

Question. The budget justifications describe your research involving ozone as a potential environmental hazard. Given the fact that most people spend the majority of their time indoors or in other enclosed spaces, please describe your research, planned or ongoing, involving potential hazards often found indoors, e.g., tetrachloroethylene from drycleaned clothing (called a positive carcinogen by the National Cancer Institute), pesticides, chloroform from tap water (suspected by the International Agency for Research on Cancer of being an animal carcinogen), radon, etc. Will your research attempt to assess the relative risks of the various indoor agents, to help prioritize further research and possible regulatory and legislative activities?

Answer. NIEHS research has been focused on many of these problems for years. Some of our major grants and university-based centers have looked at human health effects of a variety of air pollutants in both indoor and outdoor air, including the criteria air pollutants--carbon monoxide, ozone, nitrogen oxides, sulfur oxides, particles, and lead. The NIEHS-supported 6 and 24 Cities Studies have looked at many sources, including indoor air, and the

effects of unhealthy air pollution. It is the results of these studies and other related projects which are used by EPA to set almost all the air pollution criteria in place today. The 6 Cities Study gave us the new methods to measure better some of these air pollutants--especially to distinguish health effects of fine versus larger particles and acid versus sulfur dioxide, and with these methods prove the importance of the fine particles and acid.

NIEHS has been the major Federal supporter of research on the human health effects of exposure to lead and other metals. It is our studies that have been and will be used by EPA in adjusting this standard.

NIEHS-supported basic research on mechanisms of lung damage by air pollutants has developed tests to distinguish subtle effects of indoor versus outdoor air pollutants and to identify some of the susceptible populations, for example, children and asthmatics. This research will lead to new, specific, and sensitive tests for exposure and health effects of indoor air pollutants of all kinds.

The NIEHS/NTP testing program will continue to evaluate some of the many non-criteria air pollutants for their possible toxicity. These yet unevaluated chemicals will have to be chosen carefully since this testing is costly. NIEHS/NTP studies of toxicity form the basis of many regulatory actions by EPA, FDA, and others.

Question. Will your research attempt to assess the additive or synergistic effects on health of different indoor agents?

Answer. We know from past NIEHS-supported research that mixtures of air pollutants can give different health effects than the individual pollutants alone. For example, both animal and human studies implicate ozone, by synergizing the effects of aerosol acids. This "mixture" problem is very difficult to study in humans except with volunteers and "simple" mixtures. Animal studies are much easier, more reproducible, and the results are clearer. Human epidemiology studies can look for unique situations where there is a natural experiment going on. For example, the ongoing, long-term 6 and 24 Cities studies have been and will be the most helpful kind of studies to sort out all the needed information here. In the 24 Cities Study personal exposure monitoring and health surveillance are coupled with better definitions of differing exposures both indoors and outdoors to give better information on the various contributors to health effects. More studies on health effects of common aerosol mixtures are needed, especially combinations of acids with ozone and fine particles in both animals and humans.

NIEHS/NTP is also studying chemical interactions in a mixture of chemicals found at Superfund sites. This animal study has already identified super additive/synergistic effects of these chemicals in effects on the immune system. More studies on interactions of air pollutants with other chemicals are needed in which a variety of health endpoints such as effects on reproduction and neurobehavior are studied.

Question. The potential hazard of indoor radon has captured some public attention. What is the status of the 5-year study of indoor radon by Yale University, funded by NIEHS?

Answer. The NIEHS 5-year case-control study of indoor radon and lung cancer is a collaborative effort involving both Yale University and the University of Utah. Establishing and coordinating measurement protocols, setting up methods for sampling and data entry, and establishing compatible questionnaires for these two centers have gone relatively smoothly. The questionnaires are now nearly in final form and are undergoing pre-testing. Key study personnel are in place. We should be ready to begin recruiting lung cancer cases and their controls within the next 6 months.

Question. Are current risk assessments of indoor radon, used and announced principally by the U.S. Environmental Protection Agency, accurate?

Answer. The risk assessments being used by EPA are based on the best information currently available. These estimates have been developed by

extrapolating from groups of people exposed to radon in an occupational setting. In order to determine the actual risk in homes, we would need to do a large scale epidemiologic study of such populations. Until those studies can be done, we must use the current assessment.

DIOXIN

Question. Dioxin, the chemical that led to many environmental concerns and the buyout of Times Beach, Missouri, in the early 1980s, reappeared in the news recently. The U.S. Environmental Protection Agency has been criticized and praised for its efforts to reassess the degree of hazard of dioxin to human health; the apparent direction of the reassessment is to label dioxin as less hazardous to humans than previously thought. Is the EPA justified in attempting to reassess dioxin's degree of hazard?

Answer. The consensus of the Dioxin Panel of the Scientific Advisory Board was that there was no scientific reason to alter the EPA's 1985 risk assessment. However, I believe it is appropriate that EPA periodically reassess its position on the degree of hazard that dioxin presents as new information is obtained. Recent studies are shedding light on the mechanism of action of dioxin and related chemicals which will improve our ability to extrapolate the risks from animals to humans.

Question. Is the apparent direction of its reassessment justified?

Answer. EPA's assessment was based on the assumption that dioxin is a tumor promoter and that a threshold extrapolation model for risk estimation would be appropriate. Use of such a threshold-based model results in a lowering of the risk estimate, suggesting that dioxin would be less of a hazard than previously believed. However, I believe that while the scientific data demonstrate that dioxin is a tumor promoter, it also indicates that dioxin produces cancer by itself--a complete carcinogen. The EPA Dioxin Panel concluded that it would be inappropriate to regulate dioxin only on the basis of tumor promotion. In addition some members of the Panel were concerned that the revised EPA exposure limits might be within the range hazardous for reproductive outcomes.

Question. Describe the evidence which justifies the reassessment and the apparent direction of the reassessment.

Answer. The basis for the reassessment was both scientific data and science policy. There are various risk estimates ranging over several orders of magnitude that are based upon the various assumptions that can be used. The final reassessment the EPA staff settled upon was an average of the risks arrived at by their 1985 estimate and those used by other organizations involving a threshold approach. The use of a threshold approach is based upon the data indicating that dioxin is a tumor promoter, as well as basic studies indicating that a receptor mechanism is involved in the toxic, and potentially the carcinogenic, responses to dioxin. Assuming a threshold exists, EPA staff based their estimates on a biologically-based model involving multiple stages in the development of cancer. Such a model, as well as the traditional safety factor approach often used in risk assessment for threshold responses, results in a lowered degree of risk.

Question. It has been reported that dioxin can be found in various bleached paper products, such as coffee filters, paper towels, and disposable baby diapers. Describe your activities, if any, relating to dioxin in consumer paper goods.

Answer. Studies in our Institute have examined the toxicity of dioxin of rodents following oral and dermal exposure. These routes of exposure are the ones to which humans could be exposed through the use of consumer paper products. For items such as coffee filters or milk cartons, the dioxin can be leached out of the paper by the liquids, and thus can be available for ingestion. Exposure through the skin is of concern for dioxin in paper towels and disposable baby diapers. We have learned that dioxin is well absorbed from the gastrointestinal tract into the body and that dermal absorption of low doses of dioxin is more extensive than previously believed. At doses that

are environmentally relevant, as much as 40 percent of an applied dose may be absorbed through the skin. The rate of dermal absorption of dioxin, however, is quite slow. Also under investigation are studies to determine if the skin of young rats is more permeable than that of young adult rats. We have already learned that the skin of adult rats is more permeable to dioxin than is the skin of older rats.

Question. How dangerous is dioxin in consumer paper goods, as compared to the level of danger of ethylene dibromide in foods (which was banned some years ago), or to some other well-known risk?

Answer. Risk estimates have suggested that approximately 100,000 times as much ethylene dibromide (EDB) would be needed as dioxin to cause a similar incidence of cancer. The environmental exposure to dioxin is much less than to that of EDB. The levels of dioxin in paper products are in the range of parts per trillion. The bioavailability of dioxin may vary depending on the matrix. However, much of the compound would probably not be available for human exposure. On the other hand, dioxin is much more persistent, not only in the environment but in the body, than is EDB; therefore, there would be the potential for bioaccumulation leading to a cumulative toxicity upon repeated exposure to low doses.

GROUNDWATER

Question. The healthfulness of groundwater is of concern because of the number of people who must rely on it. Describe your activities relating to groundwater, especially regarding pesticides in general, and all chemicals of potentially serious hazard.

Answer. One of the most critical environmental issues today is groundwater contamination. Approximately 50 percent of the population in this country depends on groundwater as its primary source of drinking water and domestic water supplies. About 95 percent of rural Americans depend on groundwater for all their water needs; nearly 75 percent of American cities derive their supplies, in total or in part, from groundwater. The contamination of groundwater by hazardous waste disposal and application of pesticides and fertilizers is of grave concern to our society. The NIEHS/ NTP has been actively studying the possible health effects of long-term, low level exposures to chemical mixtures.

The NIEHS/NTP, through an interagency agreement with Agency for Toxic Substances and Disease Registry, has conducted over 30 studies of varying length on the health effects of a chemical mixture of 25 frequently detected contaminants in groundwater samples at or near more than 1,000 priority hazardous waste disposal sites. Among the 25 chemicals are such prime groundwater contaminants as trichloroethylene, tetrachloroethylene, chloroform, and lead. The specific areas of health effect studied, include the immune system, blood forming system, reproductive system, the nervous system, and the liver and kidneys. The potential of such a combined exposure of 25 groundwater contaminants in causing three main types of toxicity--cancer, genetic mutation, birth defect--has been or is being investigated. While the NIEHS/NTP takes the lead and is the principal institute for the development of this program, a portion of this research was carried out under collaborative effort between the NIEHS/NTP and the EPA. So far the most significant findings include the suppression of the immune system by this mixture of groundwater contaminants and the enhancement of toxicity to the blood forming system and to the liver as a result of combined exposure to other known toxicants.

As a continuing effort to study the toxicology of chemical mixtures, we are initiating studies to assess the health effects of laboratory animals exposed to three pesticide/nitrate chemical mixtures. One is a typical mixture of 19 pesticides plus nitrate; another is a mixture representing groundwater contamination in the state of California--6 pesticides plus nitrate; and the other is a mixture representing the groundwater contamination of the state of Iowa--5 herbicides plus nitrate. Ammonium nitrate was selected as the representative of fertilizer and the pesticides selected

include such well-known ones as dibromochloropropane, ethylene dibromide, aldicarb and 2,4-D.

NONASBESTOS FIBER HEALTH EFFECTS

Question. There is an active Federal program dealing with asbestos in schools. There is also much awareness about the potential hazards of asbestos. But there so far has been less attention paid to the possible health effects of fibers other than asbestos, such as glass fibers. Describe your research into the potential health effects of human exposure to fibers other than asbestos.

Answer. The NIEHS' Division of Toxicology Research and Testing has completed a number of important toxicology and carcinogenesis studies concerning fibers. These have included chronic disease inhalation studies with wollastonite and small diameter glass fibers as well as chronic feeding studies with several types of asbestos. Materials are nominated for testing based on the potential for human exposure and the severity of the suspected biological hazard.

A major ongoing research program within the Laboratory of Pulmonary Pathobiology involves the study of cellular and biochemical mechanisms leading to fibrotic lung disease. Studies concerning initial fiber disposition, uptake and translocation of particles among various cell types and anatomic compartments of the lung, the physico-chemical changes and distribution of intrapulmonary particles, and the initial cell-tissue reactions leading to disease have been completed. It is hypothesized that macrophages secrete factors which stimulate the growth of various cell types in alveolar duct regions, leading to fibrosis and obstruction of small airways.

In order to assist the NIEHS and the research community in developing long range plans for further fiber toxicology research, NIEHS is convening a workshop in July 1989. This workshop will have participation by a distinguished panel of experts. Output from this workshop will include review papers for publication and specific research recommendations useful for establishing future priorities.

Question. Do the results of your studies warrant legislative or regulatory actions at this time?

Answer. Although we do not play a regulatory role per se, we do not feel that the research is far enough along to indicate that any regulatory or legislative action is warranted at this time.

OSTEOPOROSIS AND ESTROGEN

Question. The Justifications describe your research into the relations of estrogens and osteoporosis in postmenopausal women. What are your findings?

Answer. There are many systems within the body that are affected by estrogenic hormonal agents producing a variety of effects. This hormonal signal is believed to be mediated or transmitted through an intracellular receptor protein. We have established that two osteosarcoma bone cell lines process estrogen receptor protein. This indicates that bone cells have an estrogen hormone receptor mechanism similar to that of well known estrogen target tissues as the breast, pituitary, and uterus. The presence of the receptor mechanism would also indicate that estrogen and/or estrogenic compounds can act directly on these bone cells, which had been hypothesized previously but not documented. We have tested this hormonal response further by studying estrogenic stimulation of certain specific enzymes in bone cells. In addition, exogenous genes with specific estrogen hormone responsive DNA regions have been introduced or transfected into these cells to document experimentally an estrogen specific action. When this direct estrogen action is confirmed by further experimentation, it may be possible to evaluate the potential role of hormonally active environmental estrogenic agents in the osteoporotic condition.

Question. Do your findings warrant any legislative or regulatory actions at this time?

Answer. While the basic research currently underway may eventually lead to the design of test/screening systems directly applicable to the regulatory process, the results to date are too preliminary to make any specific statement about potential legislative implications.

RESEARCH MANAGEMENT AND SUPPORT

Question. The Justifications describe some of your efforts to reduce the costs of research management and support. Describe in further detail the hardware, software, and procedures acquired, undertaken, or planned to reduce these costs.

Answer. Over the past 5 years NIEHS has implemented several improved methods of obtaining, manipulating and disseminating information as we adapt to and benefit from the rapid improvements in the computer and communications fields. The Institute has installed in most management and support offices compatible personal computers (PCs) with word processing and data management software. The improved efficiencies derived from those changes have been significant.

In our Personnel Office each specialist now uses their PC to draft and complete position descriptions, classification actions, letters and other written correspondence. Because of this, each personnel clerk now works with a team of two specialists instead of one. A personnel action tracking system has been put on-line on our main computer. This allows managerial staff to have immediate status of any of their pending actions. The Personnel Office has also adapted the improved performance and reduced costs of the FAX technology in their operation. Turnaround time, which had been 10 days to 2 weeks, is now reduced to next day availability of the certificates. Vacancies are filled more quickly; downtime is reduced; and research activities are impacted less severely.

The Institute's Financial Management Office has implemented a number of changes which now enable the on-line input and manipulation of budget data with agency headquarters. Because of the geographical separation of the Institute from the National Institutes of Health (NIH) in Bethesda, Maryland, the numerous changes always attendant with the budget formulation and justification process have been a labor intensive effort in large measure because of the logistical obstacles involved. With on-line changes now possible the process can be completed more accurately and with less effort.

The Division of Extramural Research and Training is using the same capabilities used in the Financial Management Office in its operation. Through acquisition of computers compatible with those at NIH and the availability of on-line communications links with staff in Bethesda, the grant review process has become less of a logistical problem; for instance, summary statements are much more easily completed and transmitted. Information exchange with grantee institutions has been made easier and less burdensome through the use of improved technology and availability of FAX machines.

The Institute is proud of its accomplishments in the area of adopting emerging computer and communication capabilities to its operations. As described in preceding paragraphs, the thrust of our efforts have been to improve how we communicate with others.

Question. Describe any ongoing efforts to constantly review operations to determine further ways to reduce these costs without adversely affecting research.

Answer. An area which is now receiving increased emphasis is the administration and management of our contracting and procurement activities. With the assistance of programmers and systems analysts available through a computer support contractor, we are in the process of automating our small purchases program. In addition to reducing paper flow, we also anticipate having the capabilities of identifying frequent purchases from various vendors

by more than one research division. By doing so it will be possible to combine requirements into larger procurements using, for instance, either Blanket Purchase Agreements or Indefinite Delivery Contracts. Increased use of these mechanisms accomplish several objectives. By buying in larger quantities our unit prices will be reduced; research divisions will not be required to generate individual requisitions; our Procurement Office will issue fewer individual purchase orders; and delivery times will be significantly reduced.

Similar automation efforts are beginning within the grant administration activities. It is anticipated that report generation will be made more efficient and accurate when this system is fully automated. Problem identification will also come earlier and can be dealt with in a more timely and effective manner.

Within our library, efforts are continuing to make more on-line computerized data bases available to our researchers. These efforts make literature searches less labor intensive. They also assure, as much as possible, access to the latest available citations from the literature.

QUESTIONS SUBMITTED BY SENATOR HARRY REID

COMPOSITE MATERIALS

Question. I recently held a hearing in the Toxic Substances and Environmental Oversight Subcommittee, which I chair, on the effect of composite materials on aerospace workers. The testimony I received was horrifying, yet industry continues to deny or doubt the existence of these problems. Has the Environmental Health Institute focused any research on this subject?

Answer. NIEHS has conducted or has underway toxicological studies of many of the important materials used for composites. These include studies of small diameter fibrous glass, Bisphenol A and urethane.

Materials of concern during the production and use of composites include man-made fibers, such as graphite, ceramic, and polyamide fibers, and components of the various thermoset and epoxy resins which are used, including diglycidyl ether/Bisphenol A, methylene dianiline, surfonyl dianiline, polyurethanes, and urea/phenol formaldehyde resins.

Composite materials are comprised of combinations of various plastic resins and high tensile strength, thermally stable fibers. Use of composites has increased significantly in the aerospace industry and these materials are expected to play significantly greater roles in other industries.

NATIONAL INSTITUTE ON AGING

STATEMENT OF DR. T. FRANKLIN WILLIAMS, DIRECTOR

RECENT ADVANCES

Senator HARKIN. Next we will go to the National Institute on Aging. Dr. Williams.

Dr. WILLIAMS. Mr. Chairman and members of the committee, the National Institute on Aging is the focal point in the Federal Government for aging research. This is indeed an exciting time for aging research, since both the challenges and the scientific readiness to advance have moved to a whole new level.

Let me cite a few examples. In understanding the basic mechanisms of aging, NIA-supported scientists have recently identified so-called senescent proteins which limit the growth of living cells. These proteins may also inhibit oncogenes, which, when not inhibited, lead to cancer. This has led the National Institute on Aging, in conjunction with the National Cancer Institute, to develop a research initiative in the field of cancer and aging.

In research aimed at decreasing frailty and maintaining independence, recent findings demonstrate that the usual loss of bone mass after menopause in women can be minimized by regular exercise, thus decreasing the risks for osteoporosis and hip fractures. A very notable recent finding indicates that, even in frail, 90-year-old persons, a muscle-strengthening program increases muscle mass and strength and improves walking.

Biofeedback and behavioral approaches to help people control urinary incontinence are proving quite successful, thus reducing one of the major risk factors for admission to nursing homes.

ALZHEIMER'S DISEASE

But of all the disorders associated with growing older, Alzheimer's disease is the most devastating and one of the most feared. The burdens of care and the costs in the near future will become even more catastrophic than they are today unless we can conquer this disease through research. And it is this that makes Alzheimer's disease NIA's highest priority.

Fortunately, advances being reported almost weekly are pointing to new possibilities for prevention, better diagnosis, and treatment. For example, there is now compelling evidence that nerve growth factors can correct damaged brain function in experimental animals, offering real prospects for applying this approach to the brain damage caused by Alzheimer's disease. NIA is currently sponsoring a 3-day international symposium on this subject. We now have a better understanding of possible causes of the changes in the brain proteins involved in this disease, and we can make the diagnosis more dependably during life. Within the next 3 to 4

months, we will know the results of the carefully conducted 17-center, double blind clinical trial of THA. And, as well, we have 10 to 15 additional drugs which may warrant testing. We are working to learn more about relieving the caregiver's burdens.

All of these efforts, and more, are consistent with, and strongly recommended by, the just-issued report of the congressionally established Advisory Panel on Alzheimer's Disease.

There are, of course, many other areas of challenging research in aging to which the NIA gives priority. These are outlined in my complete testimony.

I would like to close by emphasizing, as I have in previous testimonies, the key importance of training more academic leaders through such mechanisms as the newly initiated Geriatric Research and Training Centers.

PREPARED STATEMENT

Mr. Chairman, the budget request for fiscal year 1990 for the National Institute on Aging is $229,620,000, a 3.3-percent increase over fiscal year 1989, with an additional request of $870,000 for AIDS research. I would be happy to answer questions.

[The statement follows:]

STATEMENT OF DR. T. FRANKLIN WILLIAMS

The National Institute on Aging (NIA) is the focal point for the field of aging research. During the 15 years since its founding in 1974, the NIA has become a major catalyst in advancing knowledge about how people age; in differentiating between normal aging and disease states or conditions which, though common among older people, are not representative of healthy aging; and, through our coordinating and leadership role, in advancing solutions for the many biomedical, behavioral, and social problems which older Americans face today and will face in the future.

The NIA's highest priorities include Alzheimer's disease; understanding the basic mechanisms and characteristics of aging; promotion of health and effective functioning, including research on such disabling problems as osteoporosis and hip fractures; and training and career development in aging research and geriatrics. Areas of increasing interest also include research relevant to long-term care, older rural populations, AIDS as it affects older people, and international and cross-cultural studies.

Among the many disorders associated with growing older, Alzheimer's disease (AD) is one of the most devastating and most feared. With the rapidly increasing number of persons living into their eighties and nineties, among whom at least one in five face the likelihood of developing this disease, the burden of care and costs will be even more catastrophic than it is today, unless we conquer this disease through further research. Advances already made in our understanding of AD are pointing to new possibilities for diagnosis and treatment. One of these areas of important advances is related to the chemicals in the brain which transmit signals between nerve cells.

For a number of years, scientists focused on acetylcholine as the major neurotransmitter involved in memory, and therefore in AD. Now, it has been found that a second neurotransmitter, glutamate, may also play a major role. Normal levels of glutamate in the central nervous system are necessary for brain growth and development, learning, and memory; excessive levels can be toxic to selected brain cells. Recent studies have shown that the numbers of cellular receptors, or binding sites, for glutamate are substantially decreased in the areas of the brain of AD patients responsible for learning and memory. This loss of glutamate receptors, together with toxic damage to remaining cells by what may now be excessive glutamate, may be responsible for the learning and memory problems of AD patients. There are also some new, provocative clues to possible infectious agents and/or toxic substances which may produce cell damage in Alzheimer's disease.

Early and accurate diagnosis of AD has a major impact on the progress of research on the dementias most common in older people. Investigators at Washington University have now demonstrated the validity of careful clinical research diagnostic criteria for AD with 100 percent confirmation at autopsy in their group of longitudinally-followed patients, including patients first diagnosed in early stages of the disease. Other studies are aimed at identifying specific biologic tests for early diagnosis.

A number of new pharmacological agents are under study that may provide a method of treatment for at least some of the cognitive deficits in AD patients. Preliminary results will soon be available from on-going clinical trials begun in August 1987 on the safety and efficacy of tetrahydroaminoacridine (THA). Another promising lead is the use of nerve growth factor (NGF), which may help counteract the loss of neurotransmitter activity--and consequent loss of cognitive function--due to cell degeneration in AD patients. In other studies, an ordinary diet supplement, acetyl-L-carnitine (alcar), has been found to slow the loss of memory in aging rats.

In 1988, the NIA awarded the first two Leadership and Excellence in Alzheimer's Disease (LEAD) awards with three more planned to be awarded this year. The LEAD awards allow the recipients, who are all outstanding scientists, to devote a major portion of their time to research and to assisting in the development of outstanding junior biomedical investigators interested in AD and other dementias of aging. In addition, as directed by the Omnibus Health Bill of 1988, the NIA will soon be awarding a contract to establish an Alzheimer's Disease Education and Referral Center to gather, maintain, and disseminate information on Alzheimer's disease research and services.

Other NIA initiatives on Alzheimer's disease include development of a tissue bank as a resource for scientists studying the biology and genetics of the disease; expansion of the NIA Alzheimer's Disease Research Center program with three new centers; and a major drive--coordinated with the National Center for Nursing Research, the National Institute of Mental Health, and the National Center for Health Services Research--to support research on the burdens of AD caregivers and how these burdens may be eased.

In further progress on understanding the processes of aging itself, NIA-supported molecular biological studies using various cell systems are identifying proteins, messenger RNAs, and the genes which control them, which appear to be responsible for the limited life spans of cells. These genetically controlled senescent proteins may also be related to the inhibition of oncogenes which, when not inhibited, lead to cancer.

NIA intramural scientists have shown that the stress of response to heat in old rats and in cells from old rats, results in lower accumulations of the messenger RNA for heat shock protein than in younger rats. The old rats would therefore be less able to respond effectively to heat-induced stress. These studies contribute to our understanding of the age-related decline in the ability of animals to cope with environmental stress.

The increased dependence of many older people on others for support in the ordinary activities of everyday life is often the direct result of decrements which have accumulated over time. There is growing evidence that physical deficits among older people are to a considerable extent preventable or reversible. For example, deficits in muscle strength, balance, and gait contribute to functional limitations and fall-related injuries. Small-scale studies with older persons have now demonstrated that exercise regimens can retard the age-related loss of bone, increase cardiopulmonary fitness, and improve glucose tolerance. Recent

NIA-supported pilot studies have extended this work and shown encouraging improvement in very frail older persons, those aged ninety and older, with special training, including impressive increases in muscle mass and strength.

Injuries are a leading cause of disability and death in old age. Falls, the major type of injury among older persons, are associated with hip fractures, costly long-term disability, and a diminished quality of life. Falls are not, however, an inevitable consequence of aging, and can often be prevented through elimination or modification of risk factors, both in the individual older person and in his/her environment. The NIA has initiated an injury prevention and control initiative with two key emphases: First, epidemiologic research to gain a wider knowledge of the interacting biomedical, social, and behavioral risk factors for injuries; and secondly, clinical trials to test different strategies for reducing frailty and the risks of falls, and for improving recovery from falls-related injuries. This work has great potential for reducing health care costs. Reducing the incidence of hip fractures by 15 percent, for example, could save about $750 million of the currently estimated $5 billion annual costs associated with this problem.

As noted in the 1987 Institute of Medicine (IOM) report recommending geriatric centers of excellence, a sufficient number, or "critical mass," of individuals with expertise in geriatrics is required to develop future leaders in the field. In response to the IOM report, the NIA has issued a Request for Applications for Geriatric Research and Training Centers. The Institute expects to fund at least one center in FY 1989. The Institute is also initiating two awards which complement the center award, the Geriatric Research Institutional Training Award and the Geriatric Academic Program Award, which will provide a continuum of support from the fellowship to the faculty level.

The NIA has had a longstanding interest in medical, social, and behavioral aspects of long-term care for frail older persons. Current studies include research on the interactions between formal and informal health care, on active and dependent life expectancy, and on the effect of recent changes in the American family on intergenerational relationships and support capabilities; as well as the design and testing of clinical trials for biomedical, social, and behavioral interventions to reduce the need for long-term care. The NIA-supported Teaching Nursing Homes and Alzheimer's Disease Research Centers each conduct research relevant to long-term care. The NIA also supports the development of data bases, which are important in assessing older people's needs for long-term care and evaluating the effectiveness of health care services and informal supports.

An area of increasing interest is research on older rural people. Two of NIA's Established Populations for the Epidemiologic Study of the Elderly--the "Iowa 65+ Health Study" and the "Piedmont Health Survey of the Elderly" in North Carolina--are providing longitudinal information about the health and functioning of older, rural Americans; and three of the seven Alzheimer's Disease Patient Registries are collecting data on populations in rural areas. The NIA is also participating in the third National Health and Nutrition Examination Survey conducted by the National Center for

Health Statistics. Older rural, as well as urban, dwellers will be included among the 40,000 randomly selected participants. Further NIA-supported research on older rural populations will focus on such issues as the special role(s) of rural environments on the health and well-being of older residents; and the health implications and consequences of the diverse biomedical, cultural, and social features inherent in rural settings throughout the United States. The NIA is currently studying the feasibility of supporting one or more centers for the study of older rural populations.

Ten percent of all AIDS cases reported in the United States (about 7,000 cases) have involved people age 50 and over. Of these, 1,000 have been among persons over age 65. As with younger populations, unknown numbers of others are already HIV-infected from pre-1985 blood transfusions and other sources. In addition, probably because of declining immune function in many older people, AIDS appears to progress much more rapidly than among younger persons. This suggests that in the next few years, there may be a dramatic increase in those over age 50 who become sick, or die, as a result of AIDS. Nonetheless, despite the large number of older people potentially affected, almost no attention has been given them. Early in 1988, the NIA commissioned experts from across the country to analyze and report on the social and behavioral implications of AIDS for the older population; and to recommend research directions. Many of the problems identified focused on the inadequacy of available psychosocial and epidemiological data about HIV and AIDS among middle-aged and older people, as well as the need for further understanding of interrelations between AIDS and age-related changes in the immune system. International and cross-cultural studies offer opportunities for exploring the relative effects of genetic, environmental, and cultural factors on aging processes and the diseases of aging. For example, rates of Alzheimer's disease and vascular dementia vary significantly in comparisons between populations in the United States and Japan. These may reflect variable genetic predisposition to AD or environmental risk factors which vary by culture or nation, as well as possible differences in definition and reporting. The NIA continues to cooperate with the World Health Organization's Special Program for Research on Aging to develop cross-cultural studies in a variety of fields, including Alzheimer's disease, osteoporosis, and immunological changes. In addition, the NIA has established an International Database on Aging through an interagency agreement with the Bureau of the Census.

The growth of the older population, both in total numbers and as a percentage of the overall population, will affect future policy decisions governing the Federal health care system and the education and training of medical and health research personnel. Because people are living longer, and the older population as a whole is growing, we can expect a proportional rise in the incidence of chronic conditions and diseases. This will increase the financial and psychological burden of family caregiving, as well as the need for an expanded variety of health care services. Research is the only answer to the great challenge of reducing such needs in the future.

Mr. Chairman, the FY 1990 budget request for this Institute is $229,620,000. I will be hapy to answer any questions you may have.

ADVISORY PANEL ON ALZHEIMER'S DISEASE

Senator HARKIN. Thank you very much, Dr. Williams. OTA, about a month ago, suggested that $300 million should be spent on Alzheimer's in fiscal year 1990, plus another $25 million for social services research.

Dr. WILLIAMS. Yes, sir.

Senator HARKIN. Now, your budget has about $139 million?

Dr. WILLIAMS. No, sir; our budget has about $83 million. The total for fiscal year 1990 for all Federal agencies is about $139 million. In the advisory panel report, NIA's budget would be increased from $83 million to about $210 million. NIA supports about 75 percent of the research on Alzheimer's disease at NIH and the remaining portion is funded through other agencies.

Senator HARKIN. What is your view of the OTA recommendation?

Dr. WILLIAMS. I think it is a very sound recommendation.

AREAS OF SUPPORT

Senator HARKIN. Would that money, I mean, could this large increase be used?

Dr. WILLIAMS. We can certainly well justify such an increase, and we know exactly how the increase could be used.

Senator HARKIN. What would be the first area you would put it in?

Dr. WILLIAMS. We would increase our funding of research project grants in the area of Alzheimer's disease. We currently are able to fund only about 19 percent of the approved grants in this area. We would focus on finding the causes of Alzheimer's disease, improving diagnostic techniques, testing new drugs for treating Alzheimer's disease, understanding and developing more effective approaches to the burdens of care, searching for selective risk factors through cross-cultural studies, developing shared tissue resources, fully funding the Alzheimer's Disease Research Centers, increasing our support for disseminating information on Alzheimer's disease, and increasing support for leading research academicians. The advisory panel report also recomends $30 million in construction funds to strengthen the Alzheimer's Disease Research Centers' facilities which are conducting some of the most exciting Alzheimer's disease research.

DIAGNOSING ALZHEIMER'S DISEASE

Senator HARKIN. What advances have been made in the diagnosis of Alzheimer's disease? There was a report last year that the researchers at Washington University followed 26 Alzheimer's disease patients and found that they had a 100-percent accuracy on them.

Dr. WILLIAMS. Yes, sir; that finding has been very satisfying. Many of the cases in that study of Alzheimer's disease were correctly diagnosed relatively early in the progression of the disease, when it had previously been harder to be confident of the diagnosis.

The seven NIA-supported Alzheimer's disease case registries—of which one is at the University of Iowa—have worked together to develop a protocol for the differential diagnosis of Alzheimer's disease, which is also in line with the recommendations from the NIH concensus development conference on differential diagnosis of Alzheimer's disease. Using that carefully developed protocol, the group at Washington University has documented, with ultimate postmortum findings, a 100-percent success for diagnosing Alzheimer's disease.

Overall, we can be confident of 90 percent or better diagnostic accuracy in this disease, which is very important in selecting people for clinical trials, making therapeutic decisions when treating Alzheimer's patients, and informing families of the correct diagnosis.

Senator HARKIN. Ninety percent accuracy?

Dr. WILLIAMS. Yes, sir.

Senator HARKIN. That is pretty good.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

OK, Dr. Williams, thank you very much. We will have some additional questions which will be submitted for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

ALZHEIMER'S RESEARCH

Question. Alzheimer's Disease afflicts approximately 2.5 Million older Americans and costs an estimated $88 billion for the care of these individuals. Last year the Committee made significant increases to the administration's request of $109.4 million for Alzheimer's for all HHS agencies.

Based on the President's fiscal year 1990 request, approximately $139 million would be spent or $15.5 million or 11.5 percent more than last year. OTA released a report on March 31, 1989 suggesting that $300 million should be spent on Alzheimer's in fiscal year 1990 plus another $25 million for social services research.

What is your view of the OTA recommendations which would more than double Alzheimer's spending? Could this large of an increase be used?

Answer. At present, the total national expenditure for Alzheimer's disease (AD) research is a small fraction of the actual cost of care. The full capacity of the scientific community, those who are capable of working on AD and making significant contributions to our understanding of this disease, has barely been tapped. The rate-limiting factor to date has been the availability of funds and resources to work on the disease. A substantial portion of the additional funds recommended by the panel could be used to fund currently approved but unfunded high quality research projects. In addition, the availability of research funds will attract new investigators, who, at present, are working in other areas of biomedical sciences.

Question. What progress has been made on Alzheimer's with the increase provided by the Committee last year?

Answer. The additional funds provided have allowed the National Institute on Aging (NIA) to accomplish the following significant goals:

Diagnosis: The criteria and methods for diagnosing patients has substantially been improved. For example, one of the NIA supported Alzheimer's Disease Research Centers has recently reported 100 percent accurate diagnoses, in a series of 26 patients whose diagnosis was confirmed at autopsy. In addition, work on the search for positive chemical markers for the disease is making rapid progress. Many scientists believe that we will soon have a non-invasive diagnostic marker for the disease.

Treatment: The clinical trial for the efficacy of tetrahydroaminoacridine (THA) is making progress. It is anticipated that the results of the first 100 patients will be available sometime this summer. In addition, 10 to 15 new drugs are being considered for testing to determine their safety and efficacy for treating AD.

Cause: The biology of one of the abnormal proteins, amyloid protein, associated with AD is being uncovered. Scientists now have learned that, in the normal brain, fragments of proteins associated with the amyloid protein play a crucial role in the survival and maintenance of nerve cells. In addition, scientists are beginning to develop a better understanding of how cells function and why cells die in AD. Such knowledge about mechanisms of cell survival has begun to pay off by allowing scientists new approaches to treat the symptoms of this disease.

Treatment: Using animals, scientists have begun to test novel approaches to treat AD. Scientists have discovered that factors which promote the growth of nerves can also help nerve cells in the aging brain to survive longer. Also, they have found the gene that is responsible for making the nerve growth factor (NGF) protein. In one very dramatic study, scientists have inserted the gene for NGF into skin cell cultures which then produce NGF. These genetically altered skin cells, when grafted into the rat brain, produce this life-sustaining growth factor thus allowing experimentally damaged brain cells to live. This approach needs further development before it is ready for human testing; nevertheless, it provides great hope and expectation that it will lead to better methods of treating AD victims.

DIAGNOSING ALZHEIMER'S DISEASE

Question. I understand that one of the problems has been the difficulty of accurately diagnosing Alzheimer's and, for that reason, we have not been sure that we have been providing treatment and research with the patients who actually have the disease. I understand that this last year the researchers at Washington University followed 26 Alzheimer's disease patients all the way to autopsy and confirmed 100 percent accuracy in their actual clinical diagnosis. What have been the advances in the diagnosis of Alzheimer's disease, and can we now accurately diagnose early on whether or not a person actually has the disease?

Answer. First, one of the most rewarding payoffs of projects funded by NIA has been the systematic and steady improvement in our ability to diagnose AD accurately and early in the disease process. This achievement has come about through such efforts as the willingness of scientists to agree on clinical diagnostic criteria; the efforts of the Alzheimer's Disease Research Centers (ADRCs) to work collaboratively to develop and test better diagnostic instruments; the ADRCs bringing resources and scientific talents together allowing, for the first time, scientists to conduct systematic correlations between clinical information and the results of laboratory tests and autopsy; and finally, the availability of tissue, from well-characterized patients, has begun to provide molecular neurobiologists the resources to develop and test chemical markers for AD. As these efforts continue, we are optimistic that we can routinely obtain an early and accurate diagnosis for AD.

PROVIDING HELP TO THE OLDEST OLD

Question. As you know, Iowa ranks in the top three states in the country with regard to the proportion of our citizens who are 85

years old and older. How can functional limitations and frailty be reduced in this older age group?

Answer. In Iowa, as in other parts of the country, the oldest-old population, those aged 85 and over, is surprisingly large and, indeed, is growing faster than any other age group. Preliminary, but dramatic findings from NIA-supported research indicates that official Census projections may substantially underestimate how large the future cohorts of older people will be. In recent years, excellent research has been stimulated on this older population, some referring specifically to Iowa, and some referring more generally to the country at large. Research findings show that, while many of the oldest old are functionally limited and frail, the majority remain robust and independent. Moreover, findings show that even in very late life interventions can improve physical, mental, and social functioning and well-being.

NIA's concern with strategies for improving the health and effective functioning of older people began with a program announcement issued nearly a decade ago; and continuing research aims to understand precisely how frailty can be prevented and independence and productivity can be extended. Three strands of work are currently receiving special attention; these are elder-friendly environments, independence and productivity, and data bases.

Elder-Friendly Environments. Preparing meals, taking a bath, driving an automobile, and other everyday activities present serious threats to many frail older people. Human factors research, borrowed from space technology, can often protect against devastating psychological and economic consequences of such threats. Research on improvements in transportation, such as visible road signs, communication, housekeeping and work environments, health care, such as pill dispensers, and housing can help to extend working life and independent living, and to reduce the need for long-term care among the oldest-old. In this research area, an initiative is already underway to investigate the needs and problems of older drivers. A workshop, jointly sponsored by NIA, the National Highway Traffic Safety Administration, the Federal Highway Administration and the Centers for Disease Control, will be held in August 1989 to develop a research plan for this population. Additionally, the National Highway Traffic Safety Administration and NIA are collaborating on a project to obtain and relate driving practices and driving records in two populations, the Iowa 65+ Rural Health Study and the Yale Health and Aging Project. These are two of the Established Populations for Epidemiologic Studies of the Elderly, a multi-center, prospective study of 14,000 older Americans initiated to plan and conduct disease-oriented epidemiologic investigations. The data being collected on older drivers will be used to determine the impact of medical conditions and functional capability on a person's ability to drive and walk.

Independence and Productivity. NIA-supported studies are identifying specific interventions that can prevent, treat, or restore many of the disabilities widely associated with old age. Even in very old age, interventions in attitudes and behaviors can help to prevent decline and to maintain and improve both physical and intellectual functioning, thus allowing for continued

independence and productivity. This key finding has been repeatedly demonstrated in NIA-supported investigations of interventions that reduce risk-taking behaviors and life styles, reverse some intellectual declines, and compensate for decrements by building upon existing strengths. Among patients in nursing homes, several studies have demonstrated the potential for increasing health and independence by enhancing the sense of self-efficacy.

NIA supports research on prevention of physical frailty, defined as impairments in strength, mobility, and balance which diminish abilities for independent living; falls and hip fractures which are a major cause of institutionalization; urinary incontinence which is present in half of nursing home residents; and adverse effects of medications, a major problem in nursing home patients who often receive many simultaneous medications. This research has already demonstrated its potential.

Data Bases. Also, important surveys, such as the Longitudinal Study on Aging and the National Long Term Care Survey, are providing essential data for an expanding group of researchers to examine such topics as: assessments of the ability of the oldest-old to move around the community, the importance of the design of the dwelling unit to functioning, and social activities relevant to maintained independence. However, research on retirement has been severely hampered by the lack of any adequate current national data. To correct this gap in information, a new survey is planned for FY 1990 on health and retirement.

RURAL HEALTH

Question. What is the status of the Congressionally mandated feasibility study on establishing a center for studies of older rural population?

Answer. In response to requests by both the House and Senate Appropriations Committees, the NIA delivered in February, 1989, an interim report that reviewed a number of important research issues and the relative lack of adequate data resources on the health and socioeconomic characteristics of older persons living in rural America. Also in February, the NIA convened a panel of experts and consulted with other governmental and nongovernmental agencies, organizations, and experts. The final report based upon these deliberations has been submitted to Congress. The final report recommends establishing and maintaining a program of multiple centers at several sites with access to older rural populations--in order to capture the diversity within the older rural population--and a concurrent, coordinated program of investigator-initiated research.

STAFFING LEVELS

Question. Over the last five years the Institute's budget has doubled but the staffing level has been reduced by 7 percent, or approximately 30 staff. How is the current level of FTEs affecting the NIA?

Answer. A decrease in FTEs at the same time our budget has increased has had a significant impact on NIA as a whole. Research

is one means of finding answers to the many questions we have about the process of growing old. In recognition of this, Congress has given us in the last five years 40 mandates for advancing the field of aging research. We are using our staff at their highest capacity, including extensive overtime, to meet deadlines and also using contractors where we can for special services. While we welcome the opportunity to carry out these mandates, the reduction in staff has had a serious effect on our ability to do so.

OVERLAP WITH DEAFNESS INSTITUTE

Question. One of the areas studied at NIA is hearing loss. More than one in three older Americans have hearing impairment to some extent. As you know, we have now established the new Institute on Deafness. To what extent will the hearing impairment and hearing loss research, done by your Institute, overlap what is currently being planned at the Deafness Institute?

Answer. Activities for the new National Institute on Deafness and Communicative Disorders (NIDCD) call for "research into the detection, treatment, and prevention of disorders of hearing and other communication processes in the growing elderly population." Almost half of the estimated 20 million hearing impaired people in this country are aged 65 years and older; approximately 30 percent of age 65 through 74 and more than 50 percent of those over age 75 have some degree of hearing loss. Thus, support of research on hearing is an important part of the mandate of NIA.

The NIA has had an on-going interest and concern with hearing problems in older people since 1979, when NIA and the National Institute of Neurological, Communicative Disorders and Stroke (NINCDS) co-sponsored a seminar on "Hearing Problems on the Elderly." The NIA has sponsored the National Academy of Sciences (NAS) Committee on Hearing, Bioacoustics, and Biomechanics since 1980, and has commissioned this Committee to prepare a state-of-the-science report to evaluate the older listener's ability to understand speech and identify areas of scientific inquiry. The NIA also co-sponsored a workshop in March 1988, with the American Academy of Otolaryngology, Head and Neck Surgery. As a result of this workshop, a book on Geriatric Otorhinolaryngology, and a series of position papers addressing research needs, have been published. Furthermore, the NIA has issued three new training programs in geriatric otolaryngology to develop the critical base of clinical researchers needed for the advancement of this area.

In May 1988, NIA and NINCDS, along with other Federal agencies, co-sponsored a NIH "Consensus Development Conference on Cochlear Implants."

Given the impact of hearing impairments on older people, the NIA has a major commitment to support research in this area by:

- fostering research on factors that act on the older listener's ability to understand speech, including physiological aging and changes in cognitive ability and development of sensory aides;

- o encouraging research training and development in geriatric otolaryngology;

- o developing further epidemiologic research to delineate the prevalence of and risk factors for hearing and communication disorders in the aging population; and

- o linking the presence of hearing and communication problems with other neurodegenerative disorders of the elderly, especially the dementias of aging.

The new Institute is to provide for "centers especially suited to meeting the needs of the elderly." The NIA has several centers programs such as the Teaching-Nursing Home program, the Alzheimer's Disease Research Centers program, and a planned program of Geriatric Research and Training Centers. These programs have been very effective in promoting the development of geriatric and gerontologic research and will be equally helpful in the further development of research on hearing and communication problems of the older population.

As we have with other Institutes and Agencies, NIA staff will work closely and cooperatively with NIDCD staff to further programs of joint interest.

The mission of the NIA is to carry out and support research on the biomedical, behavioral, and social aspects of aging, and the special problems of the elderly. Diminished abilities to hear, understand speech, smell and taste appear to occur with age, and have important implications not only for quality of life, but also for the health and safety of older Americans. NIA will continue to focus on the hearing and other communication processes of aging, and on their biological, psychological and social components. The elucidation of the underlying physiological and cognitive mechanisms mediating normal age changes needs expanded research efforts in order to learn how the communication system ages, what can be expected as normal sensation, perception, and comprehension, and where interventions can be applied to correct age-related deficits. Such a better understanding would maintain and improve the quality of life, health, and safety of the older American, and ensure continuous effective communication skills in such a population.

ALZHEIMER'S DISEASE INFORMATION

Question. In your testimony last year you stated that your Institute was in the process of developing lay literature on Alzheimer's Disease, a directory of organizations that provide services to patients and families. Also, there were plans to develop a national clearinghouse that would provide information on Alzheimer's disease. Could you please elaborate on the status of these plans?

Answer. The National Institute on Aging is in the process of awarding a contract to establish the Alzheimer's Disease Education and Referral (ADEAR) Center. The Center will respond to inquiries through a widely publicized toll-free 800 telephone line; maintain a computerized on-line database of materials for health professionals and laypersons; and will work with existing Federal, state, and

local government and private organizations to inform and educate various related services. It is our expectation that the Center contract will be awarded before the end of this fiscal year.

We have also taken several steps in preparation for the education program. The Institute has conducted (under separate contract) a survey of the lay literature on Alzheimer's disease. The literature search identified nearly 800 fact sheets, brochures, videotapes, and films currently distributed to the lay public in the U.S. By querying national, state, and local groups, we found more than 600 programs currently serving Alzheimer families. This information will become part of the ADEAR Center's on-line database which will be accessible to the public. We plan to update this information periodically.

CLINICAL TRIALS

Question. Could you tell us the status of the clinical trials on THA (tetrahydroaminoacridine, an experimental drug used to treat Alzheimer's patients)? When do you anticipate this drug being approved by FDA for general public use? Do you have a feel of how much THA will cost?

Answer. The multi-center clinical trial on THA is designed as a double-blind study to assess the safety and effectiveness of this drug. In order to determine the minimal clinical efficacy, a total of 300 patients is needed. The study incorporates an interim analysis after the first 100 patients have completed the protocol. Should the effect of THA either prove to be negligible or strongly positive, then the study will be terminated; otherwise, the study will continue to completion. We expect results from the interim analysis to be completed by this summer. Based upon the rate of subject accrual, the full study would take about another two years.

Approval of THA, as with any drug, for general public use is the responsibility of the FDA. The FDA will evaluate all data presented by a pharmaceutical company before giving permission to market the drug. The evidence needed to support the New Drug Application (NDA) is mandated by the Federal Food, Drug, and Cosmetics Act. At this time, it is not possible to determine how much THA will cost. However, it is a relatively simple compound which has been available for a number of years, and thus should not be highly expensive.

MINORITY BIOMEDICAL SUPPORT

Question. We note that in your budget request you earmarked $446,000 in 1989 and $461,000 in 1990 for "minority biomedical research". Could you please explain exactly what this means?

Answer. The funds represent those earmarked for the NIA co-funding of research projects related to aging of minorities within the Minority Biomedical Research Program administered by the Division of Research Resources, NIH. These awards are made to institutions with a majority of minority student enrollment, and are aimed at ensuring ethnic minority groups an equal opportunity to pursue careers in biomedical research. Through this program, the NIA supports awards at a number of baccalaureate and graduate level

institutions such as Xavier University of Louisiana, Howard University, Ponce School of Medicine, Puerto Rico and Pan American University of Texas.

Question. Could you please tell us how many research grants you have awarded and are currently supporting in minority institutions?

Answer. The NIA currently supports three research grants at minority institutions. In addition, through co-funding of projects in both the Minority Biomedical Research Support (MBRS) Program and the Minority Access to Research Careers (MARC) Program, the NIA is providing support to minority institutions. However, the awards to these minority institutions are made by the Division of Research Resources and the National Institute of General Medical Sciences at NIH.

Question. Would you identify those institutions and the extent of support?

Answer. The MBRS and MARC programs received approximately $477,000 in FY 1989 from the NIA to support 10 awards to institutions including Morehouse School of Medicine, California State University at Los Angeles, Johnson C. Smith University in North Carolina, Prairie View A&M University in Texas and Howard University. NIA provides direct support to Meharry Medical College which received $151,380 in FY 1989 and Howard University, which received $87,830.

Question. Do you have plans to increase support to minority institutions? If not, why not?

Answer. The NIA anticipates increasing support to minority institutions in future years. An NIA working group has recently made recommendations for increasing the involvement of minority researchers in research on aging, some of whom are expected to be located at minority institutions. Such recommendations include the re-instatement of a small grant award program which provides funds for pilot or small scale studies. Another recommendation is to provide supplementary funding to institutional training programs for support of minority researchers. Additionally, NIA is participating in the overall NIH initiative to provide administrative supplemental funding to research project grants for support of minority researchers.

SCIENTIFIC RESEARCH MISCONDUCT

Question. Over the past few years, we have read or heard reports of scientific misconduct among scientists and medical researchers. What, if any, mechanisms do you have in place to guard against such behavior among your researchers?

Answer. Misconduct in science is defined as "fabrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research."

When an allegation is made during the review process, NIH staff are instructed to maintain documentation relevant to the issue. Scientists who are serving as consultants in peer review are reminded of the confidential nature of the peer review process and of investigatory procedures so that reputations are not put at risk and due process can proceed. The appropriate NIH office is notified as soon as an allegation seems substantial to assure that proper guidance is provided to staff and to assure continuity through subsequent stages of an investigation should one ensue. In the meantime, the Executive Secretary of the initial review group requests any additional information that may be required from the applicant. All issues must be resolved prior to issuance of an award. If issues are not resolved, the application is deferred until resolution is achieved.

After an award has been made, any allegations of misconduct are referred to a designated senior staff person in the Institute, the Associate Director for Extramural Affairs, who is responsible for investigating such matters in conjunction with the NIH Office of Scientific Integrity. This assures that all allegations are handled consistently and fairly. The Associate Director is knowledgeable about policies and procedures established by NIH and the Department and educates other Institute staff in these matters. The Director and Deputy Director, NIA, are also immediately informed of any allegations of misconduct and personally monitor all steps of the investigation.

Dr. Wyngaarden, in his testimony before the House, described regulations that are being put in place to prevent misconduct. The final rule "Responsibilities of Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science" has been approved by the Secretary of the Department of Health and Human Services and is under OMB review. The rule implements an assurance system under which all institutions applying for or receiving funds under the Public Health Service Act must have written policies and procedures that address misconduct in science. In addition, the rule reminds institutions that it is their responsibility to foster an environment that discourages scientific misconduct and that deals with allegations of misconduct in a forthright manner.

The process established at the NIA, as at the NIH, is designed to prevent misconduct and to provide guidance for dealing with allegations when they occur. NIA actively educates its grantees and staff about appropriate conduct of research, steps to foster such conduct, and what to do if misconduct or poor judgment is evident.

RURAL AGING CENTER

Question. Could you update us on the status of the proposed Rural Center for Aging Population Studies?

Answer. In response to requests by both the House and Senate Appropriations Committees, the NIA delivered in February, 1989, an interim report that reviewed a number of important research issues and the relative lack of adequate data resources on the health and socioeconomic characteristics of older persons living in rural America. Also in February, the NIA convened a panel of experts and consulted with other governmental and nongovernmental agencies,

organizations, and experts. The final report based upon these deliberations has been submitted to Congress. The final report recommends establishing and maintaining a program of multiple centers at several sites with access to older rural populations--in order to capture the diversity within the older rural population--and a concurrent, coordinated program of investigator-initiated research.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

LONG-TERM CARE RESEARCH

Question. Dr. Williams, please update us on the behavioral and social long term care research of the National Institute on Aging, and advise us on what NIA is doing concerning the long term care needs of special populations, such as the oldest old, minorities, women, and rural elderly.

Answer. In response to the FY 1987 and FY 1988 Congressional mandate to support research and research training related to long-term care needs of older people and their families, NIA has intensified its research initiative on behavioral and social aspects of long-term care. These efforts are being developed along two related tracks: specific social and behavioral aspects of institutional and non-institutional care needs of the older population in general and social and behavioral aspects of care for Alzheimer's disease patients and their caregivers. A growing portfolio is providing a scientific knowledge for understanding how social and behavioral factors influence older people's need for and use of long-term care services. For example, recent studies are documenting the nature of care needs in an aging population, showing how social and behavioral factors interact with biomedical factors in determining the need for and use of long-term care, how social and behavioral interventions can aid families in caring for older relatives at home and in preventing the need for care altogether, and that even small modifications in institutional arrangements can improve the functioning of institutionalized older persons. Emphasis is also placed on the interrelations of social and behavioral with biomedical factors, and with clinical rehabilitative efforts aimed at restoring and maintaining as much independence of function as possible.

Several important areas have been targeted for further research on behavioral and social aspects of long-term care, including family and intergenerational care; innovative forms of community and institutional care and linkages between informal and formal care systems; the relationship of health-related attitudes and self-care behaviors to long-term care; and the epidemiologic and economic bases for forecasting long-term care (LTC) needs, matching services to needs, and containing costs. Continued support of data bases are important for assessing older people's needs for long-term care and evaluating the effectiveness of health care services and informal supports.

LTC needs and services vary widely within the older population, often requiring specially targeted policy decisions. On the average, the oldest old, disadvantaged racial and ethnic

minorities, and rural older people have more disabilities and fewer LTC resources than other older people. Among older women, many are

in greater need than men for LTC, while many others are the primary providers of home care for older relatives.

NIA encourages research on special problems of each of these sub-populations. However, further specific targeted research initiatives will be needed to increase our understanding of the long-term-care needs of each, as indicated below:

Oldest-Old. Understanding the rapidly growing and rapidly changing oldest old population is a major NIA initiative. Results from projects on methods to forecast life and active life expectancy are showing that this population may increase dramatically beyond official estimates. Special attention has also been given to improving the national databases on this population. Two volumes edited by NIA staff will report the latest scientific knowledge on the oldest old and on new methods to forecast their health status and long term care needs.

Minorities. Because minorities may have social, language, or economic needs that necessitate targeted efforts, NIA is developing several initiatives for increasing research on minority aging and involvement of minority scientists in aging research. Although health problems are more widespread in disadvantaged minority populations, minorities tend to use less formal long-term care services than non-minority populations.

The NIA has continuing interest in and concern for increasing research on minority populations. For example, the NIA's Piedmont Health Survey of the Elderly is fifty percent black. In addition to investigations of well-being, health, and effective functioning in the middle and later years among African American, Hispanic, Asian, and Native American populations, this study seeks to elucidate diversity within each group arising from geographic difference, country of origin, or differences in socioeconomic level.

Over the years, projects supported by NIA have addressed various aspects of minority aging including family intergenerational relations, health, health behavior, health care utilization, culturally-specific family and non-family support networks, and other topics. Program announcements released by the NIA emphasize research on minorities through use of over sampling, subgroup analyses, or minority targeted proposals.

In 1987, four awards were made under a solicitation for Exploratory Studies in Minority Aging. Pilot projects include studies of older urban African Americans, health status and health promotion behavior among older Japanese, Chinese, and Koreans in Chicago, preliminary work for a longitudinal study of African Americans with hypertension or diabetes, and research on immunosuppressive factors among Japanese older people. As the exploratory phase of these projects concludes, applications for more in-depth study are anticipated. A major contribution of future minority-specific social and behavioral research would be to identify where long-term-care services for minority populations are needed and how to enhance or supplement the strengths of informally-delivered care in minority communities. Research is needed to

identify barriers to care, and to test interventions that could reduce such barriers as poor availability of information or referral to existing resources, economic problems, language differences, and--on the part of care providers--lack of awareness of cultural differences in health attitudes and practices.

Women. Older women far outnumber older men. Many are widowed and many live alone. An NIA conference addressed the anomaly that today in this country women live much longer but are on the average sicker than men. Based on this conference, NIA is calling the research community's attention to the implications and explanations of this relationship among gender, health, and longevity. One implication of women's poorer health is their greater need for long-term care, and current NIA-supported work is aimed at forecasting the magnitude of this need. At the same time, because women live so long and because most function effectively throughout their lives, older women are the major providers of informal health care, both for ailing husbands and for other family members. Behavioral and social research is examining how older women meet these demands for care, what stresses are involved, and what community and other support services are needed. Of immediate concern are the added demands imposed by the AIDS epidemic as sons and other younger family members increasingly return home to die.

Rural. In their FY 1989 reports, both the House and Senate Appropriations Committees have encouraged an extended program of research on the health and social needs of the older rural residents, and they requested that the NIA consider the need for and feasibility of establishing centers for studies of older rural populations. Since 1981 the NIA has supported a major epidemiological project on older rural populations in Iowa, The Iowa 65+ Health Study, and a second project was begun in North Carolina in 1984, the Piedmont Health Survey. Other NIA research has focused on social support systems in rural areas and farm family intergenerational relations. More recently information on Alzheimer's disease and other dementias is being collected in rural as well as urban settings. A broader initiative on the health of older rural residents is being planned. A panel of senior health researchers and others with expertise in aging and rural health was convened to study the feasibility of the proposed centers and to develop recommendations. An interim report was issued in February, 1989, and the NIA's final report has been submitted to Congress, which recommends that several rural health centers be established.

Older Retarded Adults. Very little is known about the rapidly increasing population of older retarded adults. NIA is issuing a program announcement in FY 1989 that calls for research on the epidemiology and demography of this population as well as research targeted at addressing their particular needs and abilities.

Other Special Populations. NIA is considering initiatives on a number of other special populations that have high degrees of vulnerability, such as those who live in board and care homes and those who have had conservators appointed to manage their affairs.

ALZHEIMER'S RESEARCH CENTERS

Question. Last year this Committee provided an increase in funding for Alzheimer's Research Centers. How many new centers will you fund in FY 89?

Answer. The National Institute on Aging plans to fund three new Alzheimer's Disease Research Centers in FY 1989, bringing our total number of these centers to 15.

Question. Will you fund any new centers under the President's FY 90 request?

Answer. No, the National Institute on Aging will not fund any new centers under the FY 1990 request. Only ongoing centers will be supported.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

STATEMENT OF DR. LAWRENCE E. SHULMAN, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Now, we will go to the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Shulman.

Dr. SHULMAN. Mr. Chairman, thank you very much. It is a great privilege to appear before you on behalf of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. I emphasize all of these areas within our Institute. We have a broad and diverse research agenda in each of these areas, addressing numerous diseases that affect millions of our population. There is hardly a family in the country that does not have one or another of these disorders.

I would like to briefly share with you some highlights of scientific advances in these fields this year. Let us start with rheumatoid arthritis. We are intensifying the search for infectious agents as initiators of rheumatoid arthritis. Last year, with your urging and with our own interest, we issued a program announcement for more research in this area. I am pleased to indicate that we have had a good response this year with additional research applications, as many as 18 new applications so far. There are other research findings in rheumatoid arthritis as well.

We are also energized to search for an infectious agent, because of the great story with respect to Lyme disease. As you know, Lyme disease was discovered as an arthritis in children in Lyme, CT. We have learned a great deal through major discoveries in Lyme disease over these past 11 to 12 years. But, there is still much we need to know. We have joined forces with the Allergy Institute in working in this whole area.

In December 1988, we put on a major scientific workshop that was highly successful. The workshop generated a new research agenda for Lyme disease. Accordingly, we are putting out request for applications and program announcements this spring in this area.

We have had a major discovery with respect to mechanisms of allergy by our Scientific Director, Dr. Metzger. It is published in the current issue of Science. There is a highlight in Science that explains it in lay terms, which says that it is "nothing to sneeze at." We are very proud of Dr. Metzger and his coworkers for 16 years of great work.

Turning our attention to the bone disease area, osteoporosis is a major disease in this country. It is the chief cause of fractures in postmenopausal women and the elderly. Over 20 million people have osteoporosis and it costs us about $10 billion a year. We have had some significant achievements. Perhaps the most striking one

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is that we have a new, better method of measuring bone density called DEXA. It is faster, more accurate, and thus cheaper than previous methods. All previous methods to measure bone mass took about 30 to 35 minutes to perform the test; this one takes only 5 minutes.

We held a major workshop on back pain which has also been highly successful. Recommendations from the workshop have been published in a book.

Turning briefly to skin diseases, you mentioned an interest in laser therapy. We have had a very interesting development in terms of tunable laser therapy for what is called port wine stains. These are disfiguring birthmarks that occur on the face.

This laser treatment is very ingenious and was developed by a small business innovation research grant that we supported. This finding was published recently in the New England Journal of Medicine and also in Newsweek. What it does, in a word, is tune the laser to the material in the blood vessel. By repeated treatments, we have been able to eradicate these disfiguring birthmarks. This is really remarkable.

There is a great deal of interest in the sunlight and ultraviolet radiation on the skin, and next week we are holding a consensus development conference on this very subject at the NIH.

PREPARED STATEMENT

We have general research themes within our Institute in which we look at connective tissue basic biology and the development of musculoskeletal fitness.

The budget proposed for our Institute next year, Mr. Chairman, is $167,334,000. I would be pleased to try to answer your questions, sir.

[The statement follows:]

STATEMENT OF DR. LAWRENCE E. SHULMAN

I am honored to have the opportunity to discuss with you some of the latest research advances and opportunities for future research initiatives by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). The Institute conducts and supports basic and clinical research on many of the most painful and debilitating diseases affecting the American people. Virtually every family in the United States is affected in some way by one or more of the diseases within the Institute's mission. We are making significant progress in understanding many of these diseases. Many challenges remain, but the progress is gratifying.

We have achieved a major scientific advance from our Intramural Research Program. Culminating 16 years of intensive research, our scientific director, Dr. Henry Metzger, and his colleagues have succeeded in cloning and sequencing the gene for the three subunits that make up the receptor for the antibody, immunoglobulin E. This receptor is the key component to which antibodies bind in allergic reactions. This discovery, in all likelihood, will lead to new methods for treating allergic disorders and for understanding the mechanisms of action of other antibodies in immune-mediated diseases.

According to recent research findings, the nervous system may play a role in causing rheumatoid arthritis. In patients with paralysis on one side of the body who then later develop rheumatoid arthritis, the arthritis does not develop or is less pronounced on the paralyzed side. Substance P, a small protein produced by nerve endings, may be the mediator of this interaction. Substance P has been shown to stimulate the cells of the joint lining to secrete both a substance that promotes inflammation and another substance that destroys cartilage and bone.

Our intramural scientists, in other research, have uncovered important hormonal differences between animals that are susceptible to induced arthritis and those that are resistant to it. The defect in the endocrine system of susceptible animals is under active study at this time. The NIAMS also organized a major scientific conference on the immunogenetics of rheumatoid arthritis and other rheumatic diseases. The conference provided a focus for this rapidly growing area. The Institute will encourage research on genetic susceptibility to arthritis along the lines recommended at the conference.

Lyme disease is being reported with increasing frequency in many parts of the country. I am very pleased to report that the NIAMS and the NIAID sponsored a very successful scientific workshop on Lyme disease in December 1988. National and international researchers in the field shared their latest results and identified research questions that must still be addressed. The NIAMS will pursue the initiatives proposed at the workshop through a comprehensive and coordinated research program.

I have advances to share with you regarding scleroderma. Scleroderma results from overproduction of collagen, causing the skin

to be hard. Recent research indicates that this may be a disease in which the immune system reacts to the body's own tissues. Scientists have recently uncovered two autoantibodies in individuals suffering from scleroderma. Other researchers have reported on several new drugs, including captopril and nifedipine, that are effective in treating the vascular component of scleroderma. Researchers are being aided by the development of an animal model, the "Tight Skin Mouse," that mimics human scleroderma. This model may enable investigators to determine factors responsible for increased accumulation of collagen in the skin in scleroderma.

Systemic lupus erythematosus, also known as SLE or lupus, is an autoimmune disease characterized by acute and chronic inflammation of various organs of the body. Through research, impressive progress has been made against this disease: nearly 95 percent of people with lupus now survive 10 years after diagnosis compared to only a 60 percent survival rate in 1965. NIAMS-supported researchers have recently reported that receptors for DNA on the surface of white blood cells were defective in patients with lupus, thereby indicating that lupus can disrupt cell function at a very fundamental level.

Sjogren's syndrome is another autoimmune disorder; it is characterized by dry eyes, dry mouth, and/or arthritis or other systemic manifestations. The NIAMS recently sponsored a broad, multidisciplinary conference, "The Many Faces of Sjogren's Syndrome," at the NIH in January 1989. Speakers provided an overview of current understanding of Sjogren's syndrome and its many manifestations, as well as strategies for improving diagnosis and treatment.

I have several advances to report on osteoporosis, the leading cause of bone fractures both in postmenopausal women and in the elderly in general. The economic burden to the Nation caused by osteoporosis has been estimated to be $7 to $10 billion each year. A new marker has been identified; levels of interleukin-1 are elevated in patients with osteoporosis, and are reduced during treatment with estrogen and progesterone. Measurement of interleukin-1 in the blood, therefore, offers promise as a new tool for noninvasive evaluation of the metabolic status of bone. Also, a useful model for the study of fracture healing has been developed this year by our intramural scientists; it is being used to investigate the role of estrogen in treating osteoporosis. In addition, a new technology, known as DEXA, is now available for measuring bone mass. This new method is much faster and more accurate than previous methods. This new technology has already been incorporated into several major studies of osteoporosis.

More than 150,000 total replacements of joints are performed each year in the United States. A new method has been developed to study the interaction between the biomaterials that are used in joint replacements and their bone environment. This new method allows observation of the body's responses to implantable biomaterials at a cellular level.

Disc disorders are a major cause of low back pain. Researchers have determined recently that degenerative biochemical changes in the disc occur early in life, in the twenties, and, moreover, these changes may alter the biomechanical properties of disc tissues. To

direct further attention on low back pain research, the NIAMS and the American Academy of Orthopaedic Surgeons sponsored a scientific workshop last May on "New Directions in Low Back Pain Research." A book will be published shortly summarizing the workshop and detailing numerous recommendations for research on low back pain in the future.

Osteoarthritis affects some 16 million Americans; it is the most common rheumatic disease. Cartilage deterioration is a key feature of joints affected by osteoarthritis. Recent investigations have described a crosslinking role for a newly discovered type of collagen, type IX collagen. An abnormality of type IX collagen may be involved in the initiation of swelling and loss of cohesiveness of the damaged cartilage found in osteoarthritis.

Basic research on muscle, supported by the NIAMS through both its intramural and its extramural programs, is providing vital information on muscle function in health and in disease. Scientists have isolated a large protein complex from muscle that plays a central role in transmitting the excitatory impulse across membranes, ensuring uniform contraction of muscle. Other researchers have made progress in determining the genetics of muscle development. These studies are of importance to the regeneration of muscle and the response of muscle to exercise. Other NIAMS-supported investigators have determined that muscles work more efficiently if exercised and, thus, delay the onset of fatigue. These benefits to muscle occur not only in well-trained athletes, but have been documented also in individuals with a limited ability to exercise.

Pemphigus is a group of severe and often fatal blistering diseases in which the skin and mucous membranes are both affected. Innovative new techniques have been employed to study this disease, and are leading to a better understanding of the disease process, identifying with greater precision the target proteins attacked by the antibodies that cause the blistering of skin in pemphigus.

I have reported to you for the last several years on the progress being made against the dreadful blistering disease, epidermolysis bullosa. I have shared with you the pieces of the story as our understanding of epidermolysis bullosa has unfolded. This year another piece of the puzzle has been revealed. It was known that the anchoring fibrils, the structures that link the two layers of skin together, were defective. We now understand that type VII collagen, which is a major component of the anchoring fibrils, is actually present but is just not incorporated into anchoring fibrils. This research provides new lines for further investigation of epidermolysis bullosa, as well as new information on the normal structure and function of skin.

There has been great public and professional interest in the effect of sunlight on skin. The NIAMS is sponsoring a Consensus Development Conference at the NIH in May 1989 on "Effect of Ultraviolet Radiation on Skin: Prevention and Treatment." The effects of photoaging, sunblockers, and the ozone layer will be discussed. Conference participants will explore the available measures for preventing overexposure and for treating its consequences.

The outermost layer of the skin performs a vital protective function for the body: it prevents loss of water from the body, and, on the other hand, keeps certain chemicals and toxic agents from getting into the body. The barrier function is provided by lipids in the skin. Scientists have recently uncovered the mechanism of lipid production by the skin and they are gaining important new insights into the nature and role of this barrier function. This will enable researchers to design more effective topical agents to replace lost water barrier function and also to foster penetration of drugs through the skin, a useful mode of treatment for some diseases.

Subacute cutaneous lupus erythematosus is a recently recognized form of lupus characterized by severe, widespread skin involvement. Patients with this form of lupus have marked sensitivity to sunlight, as well as antibodies to a particular antigen, Ro. The reason for the co-occurrence of these phenomena has been of interest. Researchers have recently demonstrated that skin cells from patients with subacute cutaneous lupus erythematosus show surface expression of the Ro antigen after exposure to ultraviolet radiation. These findings explain, therefore, the basis for the sensitivity to sunlight in patients with this form of lupus.

Last year I reported to you new avenues of research related to AIDS and the areas within the mission of our Institute. We have made some progress and have promising plans for the future. Following a scientific workshop on "Opportunities for AIDS Research in Dermatology and Rheumatology," last year the NIAMS issued two program announcements to stimulate research on rheumatic diseases and on skin diseases as they appear in AIDS patients. The response to date has been encouraging. Most patients with AIDS and many with HIV infection manifest one or more skin diseases during the course of their illness. A skin eruption has been associated with initial HIV infection. Investigators have reported recently that the immune processing cells of the outer layer of skin, the Langerhans cells, harbor the virus in HIV-infected people. Infected Langerhans cells may, therefore, serve as a reservoir for the virus, and may play a role in the spread of the virus to other tissues in the body. The NIAMS is collaborating with Walter Reed Army Medical Center to conduct basic, clinical, and epidemiologic studies of the skin changes associated with HIV infection in Army personnel. We are pleased to have this opportunity to study prospectively the frequency, spectrum, and severity of changes in the skin associated with HIV infection, and to determine whether specific skin diseases correlate with the severity of AIDS and its progression.

Mr. Chairman, the 1990 budget request for this Institute is $167,334,000. I will be pleased to answer any questions you might have.

LYME DISEASE

Senator HARKIN. Thank you very much, Dr. Shulman. Let me just ask you a little bit about Lyme disease. You share this responsibility with the infectious disease——

Dr. SHULMAN. With the Allergy and Infectious Disease Institute, yes, sir.

Senator HARKIN. I understand if Lyme disease is diagnosed early, is it 100 percent curable?

Dr. SHULMAN. If it is diagnosed early, the standard antibiotic therapy is an effective treatment. The disease is caused by a spirochetal bacterium discovered by one of NIH's brilliant intramural scientists, Dr. Burgdorfer——

Senator HARKIN. The bacteria?

Dr. SHULMAN. The bacteria. It is a spirochetal bacterium and is in the same family as the bacterium for syphillis, sir. You would, therefore, expect that ordinary antibiotics would take care of it. However, there are examples of people who have been treated with the standard course of antibiotic therapy for early disease, and have later developed some of the late manifestations of the disease. So we need a clinical trial to determine the optimal therapy for patients with early Lyme disease.

Senator HARKIN. A friend of mine, who was a former Congressman from Iowa, Congressman Berkley Bedell, has been battling Lyme disease now for, let me see, probably 4 years now.

Dr. SHULMAN. The way the disease develops is that it has early and late manifestations, and it is the late manifestations that we are worried about. As the disease unfolds, the patients develop a late arthritis resembling rheumatoid arthritis. That is why we are so keenly interested in it. We have a known bacterium—how does it produce a late arthritis?

It also produces a late neurological involvement, and that is perhaps what the Congressman may have had. It involves the nervous system. There are cases in Europe of chronic meningitis that have been going on for years that are due to this disease that were not known until recently. We need better diagnostic tests. We also need to know how it is spread.

Senator HARKIN. Ticks, I understood ticks——

Dr. SHULMAN. It is transmitted by ticks. There are different ticks in different parts of the country. It is transmitted by a certain type of tick, Ixodes dammini, both in the northeast, and, in your part of the world, in Wisconsin and Minnesota, where Lyme disease is endemic. In northern California, there is another tick that is responsible for transmitting it.

Senator HARKIN. Of course, Congressmen Bedell was an avid fisherman; he was always going fishing.

Dr. SHULMAN. It is important for people who go into tick-infested areas to wear protective clothing.

Senator HARKIN. Senator Moynihan introduced legislation to authorize $7.5 million for Lyme disease research. We are now spending about $2.5 million. Could we spend that much money?

Dr. SHULMAN. Yes, sir; I do not know exactly what the amount would be, but we could spend a good deal more than we do now. You see, this is a new disease, so we need to encourage more inves-

tigators to get into the field. We are arousing interest with both our workshop and program announcements. We could spend a good deal more, sir.

Senator HARKIN. After the common cold, low back pain affects more adults than any other disorder. I can attest to that.

Dr. SHULMAN. Yes, sir.

Senator HARKIN. What has been our progress in understanding low back pain?

Dr. SHULMAN. There is hardly a family that has not been touched by episodes of low back pain. I have had it myself; my wife has, too. The figures are that low back pain is the leading cause of limitation of activity in the United States in individuals between the ages of 17 and 44 years of age.

Research on low back pain has been fragmented. It is a difficult area, as you can well imagine, to study. It is a complicated area. As a result, we have been attempting to develop a multidisciplinary approach. To get the neurosurgeons, the neurologists, the orthopedic surgeons, the people who are interested in disks themselves, the physical therapists, the scientists of the nervous system, and the scientists of the muscles and supporting structures, together to carry out a multidisciplinary coordinated research effort.

We have recently done that together with the American Academy of Orthopedic Surgeons. In May 1988, we held a very successful workshop, which was organized in this multidisciplinary manner. The workshop has 63 recommendations for future research that has already been published in this book early in January 1989. We hope that this will be a stimulus to more research in this area.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you very much, Dr. Shulman. We will submit the balance of the questions for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

LYME DISEASE

Question. Dr. Shulman, I understand that you share responsibility with the Infectious Disease Institute for Lyme disease. If diagnosed early, it is almost 100 percent curable. When will we have a reliable diagnostic test?

Answer. If diagnosed early, antibiotic therapy is usually an effective treatment for Lyme disease. However, we have problems with diagnosing this disease early. The currently available blood tests are based on the detection of antibodies to the spirochetal bacterium that causes Lyme disease. Such diagnostic tests are positive in only about half the cases early in the disease. Researchers have been developing another type of test; one that detects an increased production of T lymphocytes, cells involved in the immune response to foreign agents, after exposure to the bacteria. This new test has detected Lyme disease in patients who test negative for the presence of antibodies. Others have recently reported the detection of antigens of the bacterium that causes Lyme disease in the urine of infected mice and humans. These two new research findings may lead to the development of a better test for earlier detection of Lyme disease.

Question. We are now funding clinical trials testing various antibiotics, and work is underway on a vaccine. Tell the Committee what progress we can expect on finding more effective treatments.

Answer. More work remains to be done to define effective treatments for the various stages of Lyme disease. Oral antibiotics, such as penicillin and tetracycline appear to be useful for treating early disease. Their use usually shortens the duration of signs and symptoms, and appears to prevent progression to the later stages in many, but not all, patients. For the later rheumatologic, neurologic, and cardiac manifestations of Lyme disease, intravenous penicillin regimens similar to those used to treat the later stages of syphilis may be needed. In patients who are allergic to penicillin or unresponsive to penicillin, ceftriaxone, a newer cephalosporin antibiotic, appears to be a useful alternative. Well-designed, controlled clinical trials are needed to address questions that remain regarding the optimal treatment of Lyme disease.

Question. About 5 percent of Lyme disease patients develop severe arthritis especially when the disease is left untreated. What success do you expect with a Lyme disease patient who develops arthritis? Is it curable? We are now spending about $2.5 million on Lyme disease research. Legislation introduced by Senator Moynihan would authorize $7.5 million. In your professional judgment how much could well be spent on Lyme disease research in fiscal year 1990?

Answer. More research is needed on the pathogenesis of Lyme disease and the nature of the inflammatory response at its various stages. Antibiotics have been shown to be effective in treating early disease manifestations; however, treatments for the later, more

serious arthritic and neurologic complications of Lyme disease need further evaluation and development. A broad range of new research recommendations emerged from a workshop sponsored by NIAMS, in collaboration with NIAID. For the NIAMS to pursue these research opportunities would cost up to an additional $4.3 million.

LYME DISEASE

Question. Dr. Shulman, what research recommendations emerged from the recent workshop on Lyme disease? Could you tell us what the Institute is doing to implement these recommendations?

Answer. The NIAMS and the NIAID cosponsored a scientific workshop on Lyme disease in December 1988. National leaders in the field, as well as scientists from abroad, discussed a number of topics, including pathogenesis, diagnosis, treatment, epidemiology, and prevention. A broad range of new research recommendations emerged from this workshop. These recommendations included:

Clinical Manifestations

- A definition of Lyme disease is needed that will be appropriate to manifestations of the disease in different organ systems, including the skin and joints.

- Patient registries for Lyme disease need to be developed at various locations in the United States and abroad to provide a more thorough clinical picture of the disease as it spreads nationally and internationally.

Pathology and Pathogenesis

- Studies should be initiated to chart the course of infection after the causative bacterium, Borrelia burgdorferi, enters humans through the bite of a tick.

- The nature of the body's immune response to the invading organism should be pursued.

- The effects of the disease on pregnancy is unknown and should be determined.

- Animal models, in which early and late clinical manifestations of disease can be observed, would provide valuable insights into this disease.

Diagnosis

- Improved diagnostic tests for detecting Borrelia burgdorferi need to be developed. There is a critical need to standardize these tests nationally and internationally.

- A delayed hypersensitivity test, similar to the widely used test for tuberculosis, would allow public screening for Borrelia burgdorferi.

Biology of Borrelia

- Improvements in laboratory techniques are needed that would permit routine isolation and culturing of Borrelia burgdorferi from patients with Lyme disease.

- Better characterization of the membrane of Borrelia burgdorferi would allow researchers to understand the interaction between this pathogenic bacterium and the human host.

Treatment

- A number of antibiotics are currently available; their effectiveness should be evaluated at all stages of Lyme disease.

- New antibiotics that interfere with the metabolism of the causative bacterium should be developed.

- In addition to antibiotic therapy, other potential therapeutic agents are needed.

Epidemiology

- Epidemiologic studies are badly needed to monitor the spread and geographic variability of Lyme disease.

- Various risk factors need to be identified and assessed for contracting Lyme disease.

- All factors critical to transmission of the causative bacterium, including the possibility of non-tick transmission, should be studied.

Ecology

- The role of various types of ticks and other possible vectors in sustaining Borrelia burgdorferi and influencing its virulence should be explored.

- The animals critical to the spread of Lyme disease, including deer, field mice, birds, and farm animals, should be identified in different geographic regions, and their influence on the transmission and virulence of Lyme disease studied.

- Tick densities in forests should be determined so that effective tick control measures can be developed.

Prevention and Vaccine Development

- The value of various prevention strategies, such as protective clothing and rodent control, should be determined.

- Education programs are needed to disseminate information about preventing exposure to tick bites.

- Research aimed at vaccine development should be pursued.

OSTEOPOROSIS

Question. Osteoporosis affects 20 million people in the United States, predominately elderly women. Fluoride and calcium combinations have been recommended to help build strong bone mass but side effects have been reported. Are there effective treatments for osteoporosis that do not have negative side effects?

Answer. Osteoporosis treatment is an important topic for current research programs of the NIAMS. A large, controlled clinical trial on fluoride treatment in osteoporosis patients is nearing completion. The findings of this study of nearly 300 patients will be reported in the fall of 1989. Other clinical and preclinical studies are also supported by the NIAMS.

No currently approved treatment for osteoporosis is without its side effects. Estrogen has a small but measurable risk for increased endometrial cancer. Calcitonin has few medical risks, but the treatment is expensive, it must be injected, and it is not effective in some 30 percent of patients.

PORT WINE BIRTHMARKS

Question. Dr. Shulman, each year we hear from public witnesses who have port wine birthmarks that cause a great deal of psychological discomfort and loss of esteem in children. I understand that new laser treatments can safely erase these birthmarks. Has this technique been perfected to the point where it is now recommended for all cases?

Answer. Indeed, a tunable dye laser has been developed and used successfully to treat port wine birthmarks, including those in young children. The birthmarks are caused by a malformation of tiny blood vessels just under the skin. When the abnormal blood vessels are treated with the tunable laser, they soak up the laser's energy, heat is generated, and the blood vessels are destroyed. This new therapy seems to erase port wine birthmarks safely and permanently. Not only can patients be spared years of emotional suffering, but also they can be spared the possibility of the abnormal blood vessels' penetrating muscle or bone, causing glaucoma if they enter the eye or seizures if they reach the brain. The tunable dye laser technique has been perfected to the point where it is among the recommended treatments for almost all cases, although the specific treatment used is still up to the patient's physician.

MUSCULOSKELETAL FITNESS AND SPORTS MEDICINE

Question. Doctor, the legislative authority for your institute requires: "Research on the refinement, development, and evaluation of devices that will substitute for damaged bone, muscle, and joints." What can you tell us about your institute's efforts in this area?

Answer. A major research effort of the NIAMS in replacement devices has focused on artificial joints. The most recent innovation in joint replacements has been the use of metals with a porous

surface to allow the ingrowth of bone. Several projects are funded to determine the mechanisms governing this attachment procedure.

Another approach to repair joints and large defects in bone is with biological replacement. Several researchers are investigating the use of autografts and allografts for surgical transplantation to replace the injured or diseased tissue. A workshop cosponsored by the NIAMS and American Academy of Orthopaedic Surgeons will be held on this topic in the fall of 1989.

Question. In the Congressional Justification you mentioned a workshop on sports medicine that was recently held with the Russians. What can you tell us about this collaborative program?

Answer. As part of the U.S.-U.S.S.R. Cooperative Program in Health, a scientific workshop on Sports Medicine was held in Moscow in October 1988. The workshop consisted of presentations and discussions by U.S. and U.S.S.R. authorities in the fields of exercise physiology, pathobiology, musculoskeletal injuries, biomechanics, and role of physical therapy and orthopaedic management in rehabilitation. I believe that the workshop served to open dialogue between our two countries in this important area of mutual interest. Useful information was exchanged, including the details of an interesting surgical procedure which the Russians have used quite successfully that was unknown in the United States. This has opened the door for continued dialogue between our two countries on musculoskeletal fitness and sports medicine.

Question. What plans does your Institute have for addressing the challenge of research on musculoskeletal fitness and sports medicine?

Answer. The NIAMS is encouraging researchers to explore fundamental questions of how the musculoskeletal system responds to various types of exercise and physical activity, focusing on health benefits and risks. Institute activities related to this field include a program announcement in FY 1987 on Musculoskeletal Fitness and Sports Medicine, a scientific workshop on Soft Tissue Injury and Repair in FY 1987, an ad hoc planning workshop with experts in the field in FY 1988, and a scientific symposium planned for May 1989 on Sports-Induced Soft Tissue Inflammation. The proceedings of this symposium will be useful not only to sports medicine physicians and their patients, but also to individuals engaging in fitness and recreational activities.

LOW BACK PAIN

Question. After the common cold, low back pain affects more adults than any other disorder. Can you report any progress in our understanding of low back pain?

Answer. Low back pain is the leading cause of limitation of activity in young adults 17 to 45 years of age. Economic losses attributed to back pain have been estimated at $16 billion each year. Men and women are affected with low back pain with approximately equal frequency.

Five major sources have been implicated as causes of low back pain: mechanical problems; injuries; acquired conditions, including scoliosis and osteoporosis; infections; and tumors. Emotional problems and stress-related tensions are believed by some to aggravate back problems.

An important new and innovative diagnostic tool is now available. Magnetic resonance imaging (MRI) is being used more widely in the diagnosis of spinal conditions. It appears to be especially beneficial for the study of soft-tissue abnormalities such as disc degeneration, protrusion, and rupture. The use of MRI for diagnosis of spinal conditions was underscored at an NIH Consensus Development Conference on this subject held in 1987.

Recently, researchers have determined that degenerative biochemical changes in the disc occur early in life, in the twenties, and, moreover, these changes may alter the biomechanical properties of disc tissues. To direct further attention to low back pain, the NIAMS and the American Academy of Orthopaedic Surgeons cosponsored a scientific workshop in FY 1988 on "New Directions in Low Back Pain Research." A book was published in February of 1989 detailing the 63 recommendations for future research. The NIAMS is planning a Program Announcement in FY 1989 to encourage additional research in the areas identified at the workshop.

SJOGREN'S SYNDROME

Question. Sjogren's syndrome is a disorder of middle-aged women characterized by dry eyes, dry mouth, joint disease, and other manifestations. In January 1989, the Institute sponsored a conference on "The Many Faces of Sjogren's Syndrome." What recommendations came out of that conference? Will you have the resources to implement?

Answer. Sjogren's syndrome is caused by the destruction of glands that secrete tears and saliva. It may be a primary disease, or it may be secondary to certain rheumatic diseases, such as rheumatoid arthritis, lupus, or scleroderma. In January 1989, the Institute held a conference to disseminate the most up-to-date information on the diagnosis and treatment of Sjogren's syndrome. Following the conference, a multidisciplinary panel of experts met to formulate a plan for further research. Several recurring themes emerged as needs and opportunities. These include a need for animal models; development of standardized diagnostic criteria; population-based studies to determine incidence and prevalence; and investigation of the role of genetic factors, the role of viruses or other infectious agents, and possible neurological or endocrine involvement in immune regulation.

RESEARCH ON CHILDREN'S HEALTH PROBLEMS

Question. What portion of the NIAMS budget is being devoted to research on children's health problems and their prevention? What are some of these areas of research?

Answer. One cannot readily break out research efforts that are devoted to children's health problems and their prevention versus

those in adults. Our arthritis research effort, for example includes studies of the inflammatory process, of collagen metabolism, and immunogenetics. This research is relevant to both the juvenile and the adult forms of arthritis.

The NIAMS does support research in areas that affect mostly children. Some examples include:

- Epidermolysis Bullosa. Epidermolysis bullosa (EB) is a tragic group of genetic disorders, causing blistering in infants and children and destruction of skin and mucous membranes resembling severe burns. A particular type of collagen, type VII, had been identified as a major component of the anchoring fibrils, which link the outer layer of the skin to the inner layer. This year, research utilizing a new monoclonal antibody has revealed that, in EB, type VII collagen is, in fact, present, but is not incorporated into anchoring fibrils. This leads the research on EB into new directions.

- Arthritis in Children. Considerable progress is being achieved on the immunogenetic basis for investigating arthritis in children. Researchers have found that juvenile arthritis is associated with several tissue-type antigens, suggesting a link between juvenile arthritis and genetic factors. If susceptibility to the disease can be identified with a region of a particular gene, new therapeutic interventions may be possible. Also, studies addressing the functional disability of children afflicted with arthritis are leading to more effectively targeted treatment with the goal of diminishing the physical and emotional scars that often accompany the disease.

- Osteogenesis Imperfecta. Osteogenesis imperfecta is a genetic disease of children causing fragile bones with premature bone fractures, and additional defects in other organs that consist largely of connective tissues. Research on osteogenesis imperfecta has moved from the laboratory into clinical practice. A thorough study was performed, tracing the family genealogy and collagen defects of all available members of a family with osteogenesis imperfecta. Using important tools of molecular biology, the tudy confirmed that the gene mutations were located in the same regions as those that had been predicted. Researchers now have the capacity to identify defective genes for osteogenesis imperfecta in both parents and offspring.

RHEUMATOID ARTHRITIS

Question. What progress has been made in the search for a possible infectious agent as a cause of rheumatoid arthritis?

Answer. The Institute has supported research in several areas related to the infectious theory of arthritis with respect to rheumatoid arthritis and related disorders. An arthritis resembling rheumatoid arthritis in its clinical, pathological, and immunological characteristics can now be induced in susceptible rats by injecting them with cell wall fragments from streptococci and lactobacilli bacteria. Scientists in our intramural program have recently identified significant differences in metabolism between rats that

are susceptible to this bacterial cell wall induced arthritis and those that are resistant to it. This animal model has the potential to reveal how hormonal and other regulatory factors may be involved in development of arthritis in rats induced by components of infectious agents.

Lyme disease is now known to be caused by a spirochetal bacterium, called Borrelia burgdorferi. An arthritis similar to rheumatoid arthritis is one of the late manifestations of Lyme disease. Because bacteria are very difficult to recover or find in the inflamed joints of patients with Lyme disease, it is believed that some other mechanism, such as an immune reaction, may be involved in the development of Lyme arthritis. Efforts to elucidate these mechanisms have not yet been successful; there are interesting leads and research in these areas will continue.

Epidemiological studies suggest that arthritis of the spine, ankylosing spondylitis, may be preceded by episodes of bacterial infection. A bacterium with the same amino acid sequence as a protein genetic marker has been found in patients with ankylosing spondylitis. This molecular mimicry indicates that an infection initiates an immune response that reacts not only with the microbe, but also with components of the body. Studies have shown that Alaskan Eskimos and Siberians have an unusually high prevalence of this form of arthritis. They also share common ancestors and genes. The bacterial spectrum to which these populations are exposed may differ because the groups are isolated geographically. Working with Soviet scientists, we are planning a comparative study of these populations in an effort to elucidate the role of infectious agents and genetic factors in the development of this type of arthritis.

Question. Are any particular bacteria, viruses, or mycoplasmas showing up in such research?

Answer. Infectious agents that are candidates for causal roles in arthritis include bacteria, mycoplasmas, and viruses. A parvovirus has been found in some patients with rheumatoid arthritis. The immune system of patients with rheumatoid arthritis is known to respond poorly to infection by Epstein-Barr virus. Recent studies have revealed a similarity between binding sites for various bacteria and the binding sites for IgG rheumatoid factor. Research has also shown that mycoplasmas cause arthritis in some animal species. Very recently, bacteria, named Yersinia, have been found in joint fluids of patients with reactive arthritis.

Question. Some investigators have used antibiotics against rheumatoid arthritis, with at least anecdotally reported success. What studies are you undertaking to evaluate the usefulness of such treatments?

Answer. We are now mounting a new initiative to test the efficacy and safety of minocycline, a tetracycline antibiotic, in treating arthritis in view of findings reported by investigators supported by the NIDR, together with corroborating basic work by NIAMS-supported researchers. It was found that minocycline inhibited collagenase--an enzyme that is harmful to joints--both in laboratory animals and in the joints of patients with rheumatoid arthritis. The

NIAMS is now issuing a request for proposals for contracts to conduct a clinical trial aimed at determining whether minocycline is of value from this standpoint in treating patients with rheumatoid arthritis.

SCLERODERMA

Question. Doctor, are there any new findings in the area of scleroderma that offer hope to those suffering from this devastating disease?

Answer. Scleroderma means "hard skin," which is one of its most striking visible symptoms. It may also affect blood vessels and various internal organs. Procedures for ultrasound measurement of skin thickness were recently developed by investigators supported by the NIAMS. This painless, noninvasive, new technique is useful for studying the effects of therapeutic agents that might be efficacious for treating this disease.

Scientists working in the field have identified two new abnormal antibodies in patients with various manifestations of scleroderma. In the type of scleroderma where there are extensive skin manifestations, one of these abnormal antibodies was found to be prevalent. The other abnormal antibody was found in the type of scleroderma characterized by microvascular disease and minimal skin manifestations. Because these two abnormal antibodies are mutually exclusive, they have the potential of being useful clinically in diagnosing patients with the two types of scleroderma.

Other researchers have reported on several new drugs, including captopril and nifedipine, that are effective in treating the vascular component of scleroderma.

A promising animal model for study of scleroderma has been developed. It is known as the "Tight Skin Mouse". This inbred strain of mice reproduces one of the cardinal characteristics of scleroderma, increased accumulation of collagen in the skin. With this model, it should be possible to elucidate the events responsible for increased accumulation of collagen in the skin.

NIAMS OPERATIONS

Question. Your Institute is now in its third full year of operation. Are you carrying on all administrative functions independently at this point?

Answer. I am pleased to report to you that in our third year of operations we are carrying on nearly all administrative functions independently from the parent Institute .

Question. Are you fully staffed in grants management?

Answer. We have the essential core staff in grants management necessary to award and process our grant portfolio.

Question. What progress have you made on developing your National Plan?

Answer. The breadth of issues that fall under this Institute is perhaps the broadest of any at the NIH. Currently, the Institute is operating under the guidance of three comprehensive planning documents, the 1976 report of the National Commission on Arthritis and Musculoskeletal Diseases; the analysis of research priorities in dermatology published in 1984; and an extensive evaluation of the musculoskeletal diseases program undertaken in 1984. These have provided an excellent blueprint for directing the allocation of resources for research in arthritis and musculoskeletal and skin diseases. Each of these documents took one to three years to prepare.

More recently, the Institute's planning process has concentrated on areas that have shown exceptional opportunity for advancement. The introduction of new technologies, especially those in molecular and cellular biology has opened new horizons for research. We have addressed these opportunities through a series of scientific workshops to which we have invited the leading experts in each field. This is a vital part of the development of a comprehensive plan.

Since 1987 we have held major workshops in osteoporosis, osteoarthritis, sports medicine, immunogenetics, AIDS, low back pain, Lyme disease and Sjogren's syndrome. This year we have workshops planned on sports-induced soft tissue inflammation, effects of sunlight on the skin, molecular biology of autoimmunity, psoriasis, and Paget's disease. A major conference on inherited connective tissue disorders is also planned for 1991. Each workshop has resulted in a set of recommendations that have been published with a summary of the proceedings and/or incorporated into program announcements designed to stimulate additional research.

I am excited by the prospect of preparing a national plan to cover arthritis and musculoskeletal and skin diseases, one that addresses the ways and means for expanding, intensifying, and coordinating the activities of the Institute. This will be a large undertaking, and will involve institute staff and outside consultants working on a number of task forces. Effort will also be devoted to receiving public comment and input into the plan.

Such an overall effort is expensive, both in staff time and money. We have developed a lean, but good staff over the past two years, and I am now recruiting two senior officials, a Deputy Director of the Institute, and a Director of the Extramural Program, who can work with me in this important effort.

INTRAMURAL PROGRAM

Question. You spoke last year of beginning to develop your Intramural Research Program Plan. How much of an expansion does it represent over the intramural research that was conducted in your program areas when you were part of the former National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases?

Answer. The FY 1990 President's request includes $10.4 million for our Intramural Research Program. This compares to $6.3 million in FY 1986, the last year that the NIAMS was part of the former

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Question. Have you needed to hire additional scientists for your intramural program? Have you been able to attract the investigators you need?

Answer. Since the NIAMS was established in FY 1987, we have been able to hire a modest number of additional scientists for the Intramural Research Program within our FTE ceilings. We are experiencing a decrease in the number of interested applicants in response to advertisements for recruitment of young scientists for our research program.

TRAINING

Question. Are you satisfied with the size and quality of the pool of young investigators who are in training to do research in the areas of your Institute's responsibilities?

Answer. Under the FY 1990 President's request, the NIAMS would support 194 trainees, the same number of trainees as in FY 1989. Implementation of the NIH initiated stipend increase resulted in a decrease of approximately 44 trainees from the FY 1988 level. However, a proposed reprogramming request would allow the NIAMS to fund approximately 21 additional trainees returning the level of trainee support to the FY 1988 level. Maintaining a cadre of skilled scientific investigators is critical to the mission of the Institute.

Question. Do you have problems attracting qualified young researchers? If so, what factors contribute to the difficulties?

Answer. The increased stipend levels for National Research Service Awards should help alleviate some of the problems in attracting the most qualified applicants, including clinical investigators.

Question. What has been the impact of the increase in the stipend level for National Research Service Awards?

Answer. The implementation of the NIH initiated stipend increase resulted in a decrease of approximately 44 trainees from the FY 1988 level of 238 trainees. A proposed reprogramming request would allow the NIAMS to fund approximately 21 additional trainees, for an estimated total of 215 trainees.

RESEARCH PROJECT GRANTS

Question. Doctor Shulman, what percentage of approved research project grants would be funded under the FY 1990 budget request? How does this compare to FY 1988 and 1989?

Answer. Under the FY 1990 budget request, the NIAMS would fund approximately 16.7 percent of approved research project grants. This compares to an estimated award rate of 26.8 percent in FY 1989 and an actual award rate of 28 percent in FY 1988.

Question. How does your Institute's award rate compare with the overall NIH award rate?

Answer. In FY 1990, the NIAMS estimated award rate of 16.7 percent compares to an NIH award rate of 24.3 percent. In FY 1989 the NIAMS estimated award rate of 26.8 percent compares to an NIH award rate of 29.2 percent. IN FY 1988 the actual award rate for NIAMS of 28 percent compares to the NIH actual of 35.3.

Question. Doctor Shulman, what would the payline be at your FY 1990 request level and how does that compare with FY 1988 and 1989?

Answer. The estimated payline at the FY 1990 request is 140. This compares to an estimated payline of 150 for FY 1989 and an actual payline of 149 for FY 1988.

INTRAMURAL RESEARCH

Question. Doctor, would you please tell us how your intramural research program has developed in the past year and what your future plans are with regard to further intramural expansion?

Answer. Our Intramural Research Program continues to develop; many new research findings emerged during the past year. Culminating 16 years of intensive research, our scientific director, Dr. Henry Metzger, and his colleagues have succeeded in cloning and sequencing the gene for the three subunits that make up the receptor for the antibody, immunoglobulin E (IgE). This receptor is the key component to which antibodies bind in allergic reactions. This landmark accomplishment holds great promise not only for developing better ways to treat allergies, but also for discovering mechanisms of action of other antibodies in immune-mediated diseases.

NIAMS intramural scientists continue to investigate inbred strains of mice that spontaneously develop an autoimmune disease resembling human lupus, in order to further analyze the genetic and biochemical basis for systemic lupus erythematosus. Recently they found that the number of cells producing autoantibodies increases with age, both in the autoimmune and normal strains of mice. The increase was earlier and greater in the autoimmune strains clearly indicating that there is preferential, antigen-dependent autoantibody production in the autoimmune strain of mice. Investigation into this phenomenon will continue to gain a better understanding of factors causing the production of autoantibodies in lupus. These are just two examples of the productive scientific investigations taking place in our Intramural Research Program.

In February 1988, the NIAMS submitted to the Senate a plan for expansion of its intramural program. Implementation of this plan appears one step closer now that the NIAMS Intramural Research Program has been assigned additional laboratory space. The NIAMS plans to establish a new Laboratory of Connective Tissue Biology. Six new basic research areas are envisioned: structural biology, cellular receptors, molecular biology, connective tissue biology, growth factors, and microbiology. These basic research endeavors would underpin new clinical research in osteoporosis, osteoarthritis, scleroderma, and exercise physiology.

Question. Do you have sufficient staff and space to carry out your intramural research program?

Answer. During this past year, physical facilities have been significantly improved and developed. The Institute's Orthopaedic Research Unit has just moved to the NIH Clinical Center, where it occupies contiguous space with the Arthritis and Rheumatism Branch. This move allows for greater interactions among NIAMS scientists.

A major piece of new laboratory equipment was recently installed within the NIAMS Laboratory of Physical Biology. It is an electron microscope with continuous imaging and other capabilities. This complex instrument will be used to study various tissues, including the molecular constituents of membranes of the human immunodeficiency virus--the causative agent of AIDS.

The NIAMS submitted to the Senate a plan for expansion of its intramural program. Implementation of this plan appears one step closer now that the NIAMS Intramural Research Program has been assigned additional laboratory space.

QUESTION SUBMITTED BY SENATOR ARLEN SPECTER

RESEARCH PROJECT GRANTS

Question. Dr. Shulman, as you know, last year this Committee expressed concern about the percentage of approved grants which are funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases. What percentage of approved grants were you able to fund in FY89? How many will you fund in FY90?

Answer. According to current estimates, the NIAMS will fund 26.8 percent of approved research project grants in FY 1989. In FY 1990, it is projected that the NIAMS would fund 16.7 percent of approved research project grants.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

EPIDERMOLYSIS BULLOSA

Question. Dr. Shulman, as you know, this Committee has been encouraging your Institute to pursue research related to epidermolysis bullosa (EB). Would you please update this Committee on the latest developments in research for EB?

Answer. Epidermolysis bullosa ((EB) is a severe blistering skin disease involving the skin and the mucous membranes. A particular type of collagen, type VII, had been identified as a major component of the anchoring fibrils, which link the outer layer of the skin to the inner layer. This year research utilizing a new monoclonal antibody has revealed that, in EB, type VII collagen is, in fact, present, but is not incorporated into anchoring fibrils. This leads the research on EB into new directions.

Question. How much will you spend on EB in FY 1989?

Answer. In FY 1989 the NIAMS is estimated to spend $3.7 million for epidermolysis bullosa.

Question. How much is included in the President's FY 1990 request?

Answer. The FY 1990 President's request includes an estimated $3.9 million for epidermolysis bullosa.

DIVISION OF RESEARCH RESOURCES

STATEMENT OF DR. ROBERT A. WHITNEY, JR., ACTING DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Next we will turn to the Division of Research Resources. Dr. Whitney.

Dr. WHITNEY. Thank you, Mr. Chairman. The Division of Research Resources awards NIH's major grants and contracts to develop, maintain, and administer essential research environments and sophisticated instrumentation programs which underpin almost all of the exciting research results you have heard here today.

Our largest program, the Clinical Research Program, supports the 78 geographically distinct, general clinical research centers located chiefly within hospitals of academic medical centers. These centers form a network of unique facilities where scientists study normal physiology and disease processes in adult and in pediatric patients.

Another major program, the Biomedical Research Technology Program, enables scientists to develop advanced technological applications of the physical, mathematical, engineering, and computer sciences to solve biomedical research problems.

Our Laboratory Animal Sciences and Primate Research Program supports research and training programs which focus on development and appropriate use of mammalian, nonmammalian, and nonanimal models, which are crucial to the success of biomedical research. At the seven regional primate research centers, over 1,300 core and collaborative investigators use nonhuman primates to study important human and animal health problems. This program continues its support of the laboratory animal diagnostic centers, post-doctorate training of laboratory animal veterinarians, and improvement of laboratory animal facilities in hundreds of research institutions.

Since 1989, the program has expanded its Biological Models and Materials Resources section, which develops and supports nonmammalian model systems and provides critical biological materials for biomedical research.

DRR's Biomedical Research Support Program strengthens institutional capabilities for research in the health sciences. The oldest of its components, the Biomedical Research Support Formula Grant, which has provided the flexible funds with which the grantees decide the emphasis and direction of their biomedical research efforts, is proposed to be eliminated.

However, both the Shared Instrumentation Grants, which are used to acquire state-of-the-art instrumentation, costing between $100,000 and $400,000 to be shared by groups of PHS-supported sci-

entists, and the Minority High School Student Research Apprenticeship Program, which provides health-related research experience to minority high school students at institutions with BRSG or MBRS funding, will continue in fiscal year 1990.

The Minority Biomedical Research Support Program enables faculty and students at minority institutions and other institutions with large numbers of minority students to participate in biomedical research and related scholarly activities. This program, along with the other minority programs, will receive a 3.4-percent increase in fiscal year 1990.

We are also awarding approximately 50 Research Facilities Improvement Program grants in fiscal year 1989 for the repair, renovation, modernization, and expansion of existing facilities at institutions where AIDS or AIDS-related research is conducted.

PREPARED STATEMENT

Some of this money is being used for the very special facilities needed to house the Severe Combined Immunodeficient [SCID] mice that Dr. Fauci referred to earlier today as an exciting breakthrough in AIDS research. No funds are requested for continuation of this program in 1990. The fiscal year 1990 request is $263,313,000 for DRR non-AIDS programs, which underpin all other NIH extramural research. This is a 16-percent decrease from the comparable fiscal year 1989 level.

[The statement follows:]

STATEMENT OF DR. ROBERT A. WHITNEY, JR.

Mr. Chairman and Members of the Committee: As Acting Director of the Division of Research Resources, I am pleased to present the President's request for the fiscal year 1990 appropriation for the Division of Research Resources (DRR). This Division has served the National Institutes of Health since 1962 by awarding grants and contracts to develop, maintain, and administer the research environments and sophisticated instrumentation programs that are essential for investigators to conduct modern biomedical research. I will briefly describe each program.

First, let me report the status of NIH's proposal to relocate some of DRR's extramural program activities. The NIH Director commissioned a task force, consisting of several Institute and Division directors, and other highly placed officials, and chaired by the NIH Deputy Director, to examine alternative organizational locations for several NIH programs including DRR's Clinical Research, Minority Biomedical Research Support, and Biomedical Research Technology programs. Comments and points of view were solicited from advisory council and committee members, extramural scientists, and other people interested in the outcome of these decisions. The Task Force's interim recommendations were circulated widely for final comment. The NIH Director approved the Task Force's recommendations to keep the Clinical Research, Biomedical Research Technology and Research Centers in Minority Institutions programs in the DRR. In addition, he approved transferring the Minority Biomedical Research Support Program to the National Institute of General Medical Sciences (NIGMS). A companion proposal to merge DRR with the Division of Research Services will be decided by the Secretary.

The Clinical Research Program supports 78 geographically distinct units either within hospitals of academic medical centers, or within research oriented institutions. These centers form a network of unique facilities where scientists study normal physiology and disease processes in adult and pediatric subjects. The centers provide both inpatient and outpatient research facilities, along with specialized laboratories and facilities for computerized data management and analyses. Specially trained research nurses and other paramedical staff assist in facilitating high quality clinical research. The centers also provide the opportunity for junior physicians to enter clinical research careers through the Clinical Associate Physician (CAP) program.

In 1988, more than 6,650 scientists used these centers for 4,610 of their research projects. These researchers received nearly $512 million of funding from NIH Institutes, and over $140 million from other sources. The network of General Clinical Research Centers (GCRCs) will continue to be an invaluable interface between basic and clinical research.

The centers continue to host an ever increasing array of AIDS-related research protocols of both children and adults. Other research has focussed on the development of a new drug, tin protoporphyrin, to prevent severe jaundice in newborn babies. The new treatment is less expensive than other therapies now available and can be used to treat infants in lesser developed areas of the world. Another group of GCRC investigators developed a slow-

release form of sodium fluoride to treat postmenopausal women with osteoporosis. Affected women are at increased risk for fracturing the bones of their backs. This is a major advance in this costly disorder, since other therapeutic approaches have been either associated with undesirable side effects or insignificant therapeutic benefits. The cost of this new therapy is approximately one dollar per day.

The Biomedical Research Technology Program enables scientists to develop and share advanced technological applications of the physical, mathematical, engineering, and computer sciences to biomedical research problems. Among the many different research areas supported are mathematical modeling and simulation of biological and physiological systems; image processing, analysis and construction; nucleic acid and protein sequence data analysis; development of microelectronic transducers and sensors which can be implanted in animal and human patients; mass spectrometry to study molecular structure; high field nuclear magnetic resonance spectroscopy to study protein structure; in vivo magnetic resonance imaging or spectroscopy of organs and tissues; techniques using X-ray diffraction and synchrotron radiation for studying protein structure; high and intermediate voltage electron microscopy for examining the three-dimensional structure of cells; electron and X-ray probes to analyze cell components; and flow cytometry to separate cellular and subcellular components. Here are two brief examples of these resources. Some cases of diabetes mellitus are the result of a genetic mutation of a single amino acid residue in the insulin molecule. Nuclear magnetic resonance spectroscopy can discern subtle changes in the way the abnormal insulin molecule folds and prevents the altered insulin from binding to specific areas on the surface of insulin-responsive cells. These studies will provide a better understanding of how insulin normally interacts with its specific binding sites on cells and may provide approaches to treating some patients with poorly controlled diabetes.

Other investigators have developed a technique to quantify changes in single cells exposed to cancer therapy. After they initially sort individual cells from a mixture in solution, the cells are exposed to a combination of three to four laser beams to detect changes in RNA, DNA and protein induced by chemotherapy. This technology may help investigators optimize effective treatment of cancer patients by selecting one or more chemotherapeutic agents.

Through our Laboratory Animal Sciences and Primate Research (LASPR) Program, we support the Regional Primate Research Centers, Laboratory Animal Sciences Centers, a variety of research and training programs, and the Biological Models and Materials Resources activities.

At the seven Regional Primate Research Centers, over 1,300 core and collaborative investigators use nonhuman primates to study important human and animal health problems. Examples include drug dependence and the behavioral effects of abuse substances; hyaline membrane disease, the most common life-threatening problem of prematurely-born infants; and AIDS using the macaque infected with Simian Immunodeficiency Virus (SIV), a virus which has many

features in common with HIV and induces a syndrome in macaques remarkably similar to AIDS in man.

The Laboratory Animal Sciences Program makes research, resource and training grants to (1) identify and develop new animal models of human disease, (2) support special animal colonies, (3) examine important laboratory animal diseases, (4) diagnose and control diseases in animal colonies, (5) improve laboratory animal facilities, and (6) train veterinary specialists in laboratory animal medicine.

The LASPR Program continues to support Biological Models and Materials Resources, thereby assuring development and support for nonmammalian model systems, along with providing critical biological materials for biomedical research. Research with cell cultures, lower organisms and nonbiological systems contribute important results while reducing the need for the use of vertebrate animals in research.

This budget request will allow us to continue the important progress in postdoctoral training of laboratory animal veterinarians, to improve facilities in several of the hundreds of research institutions at which scientists require animals in their research, and to renovate and repair the Regional Primate Research Centers.

The NIH has designed the three subactivities of the Biomedical Research Support Program to strengthen institutional research in the health sciences. The oldest of these, the Biomedical Research Support Grant (BRSG), provides flexible funds with which the grantees decide the emphasis and direction of their biomedical research efforts. Principal uses of BRSG funds include pilot studies, interim support for active research programs, young investigator support, and support of central resources. The request proposes elimination of the Biomedical Research Support Grant Program in 1990. In view of the continuing emphasis on investigator-initiated research as the most appropriate form of support, the BRSG program is of lower priority when compared to other programs that permit the directing of research funds to specific target areas.

The second subactivity is Shared Instrumentation Grants (SIG), which are awarded to institutions which receive BRSG funds. The SIGs are used to acquire state-of-the-art instrumentation costing between $100,000 and $400,000, to be shared by groups of PHS-supported scientists. This program, begun in 1982, will have awarded over 1,000 grants, for nearly $195 million by the end of fiscal year 1989. This budget request includes $31.8 million for continuation of this program in fiscal year 1990.

The Minority High School Student Research Apprentice Program (MHSSRAP) provides health-related research experience to minority high school students at institutions with BRSG or MBRS funding. NIH's only such extramural program, it is designed with the expectation that many of these students will choose careers in the biomedical sciences. Between 1980 and 1988, nearly 7,000 apprentices have experienced eight weeks of hands-on work in basic and clinical laboratories across the country. It is estimated that

2,000 additional students will have participated in this program by the end of fiscal year 1990.

The Minority Biomedical Research Support (MBRS) Program enables faculty and students at minority institutions, and other institutions with large numbers of minority students, to participate in biomedical research and related scholarly activities. This budget request includes a 3.4% increase over the comparable 1989 level. It is estimated that approximately 1,100 undergraduate and 400 graduate students, as well as 750 faculty members will receive support through 730 projects. These grants have major support from DRR, other components of the NIH, and the Alcohol, Drug Abuse and Mental Health Administration. Almost 80 percent of MBRS graduates continue study toward an advanced degree in science or the health professions. As I mentioned earlier, this program is being moved from DRR to NIGMS.

The Research Facilities Improvement (RFI) Program was initiated in 1988 to provide for the repair, renovation, modernization, and expansion of existing facilities at institutions where AIDS or AIDS-related research is conducted. The program was announced in April 1988, with a July 15, 1988 deadline for receipt of applications. One hundred fifteen applications from 110 separate institutions requesting more than $94 million were received and reviewed. From this pool of applications, forty awards, at a cost of $24.5 million, have been made so far in 1989. We expect to make approximately 50 awards for a total of $28.9 million. No funds are requested for continuation of this program in 1990. Here are some examples of RFIP awards that have been made.

Infants and children who have been exposed to the AIDS virus are a tragic and growing component of the AIDS epidemic. The RFI Program has funded two outpatient clinics, attached to clinical research centers, which will be used for evaluation of AIDS therapy in children and for research to discover new treatments.

One of the difficulties in AIDS research is the absence of a good animal model for the disease. AIDS facilities grants have been awarded for containment housing facilities for Macaque Monkeys with the simian immunodeficiency virus (SIV) infections and chimpanzees infected with the human immunodeficiency virus (HIV).

Discovery of drugs for the treatment of AIDS is a major research area supported by the NIH. A group at the Worcester Foundation for Experimental Biology in Massachusetts has discovered a class of drugs which seem to block virus replication. The DRR has funded a grant for facilities and equipment to scale up the preparation of these drugs and initiate toxicity studies leading towards human studies of the drugs for the treatment of AIDS.

The FY 1990 request is $263,313,000 for these DRR programs. I will be pleased to respond to any questions you may have.

BIOGRAPHY OF DR. ROBERT A. WHITNEY, JR.

Birthdate: July 27, 1935 - Oklahoma City, Oklahoma

Education: B.S., Oklahoma State University, 1958; D.V.M., Oklahoma State University College of Veterinary Medicine, 1959; M.S. (Pharmacology), The Ohio State University, Graduate School, 1965; Resident in Laboratory Animal Medicine, The Ohio State University College of Medicine, 1965.

Professional History: 1988 to present, Acting Director, Division of Research Resources, NIH; 1987 to present, Director, Office of Animal Care and Use, NIH; 1985 to present, Director, Division of Research Services (DRS), NIH; 1984 to present, Chief Veterinary Officer, U.S. Public Health Service (USPHS); 1984 to present, Chairman, U.S. Government Interagency Research Animal Committee (IRAC); 1984-1985, Acting Director, DRS, NIH; 1972-1985, Chief, Veterinary Resources Branch, DRS, NIH.

Uniformed Service: 1971 to present, U.S. Public Health Service, Assistant Surgeon General (Rear Admiral, 07); 1959-1971, United States Army (Lieutenant Colonel, 05).

Societies and Associations: American Association for Laboratory Animal Science; American Association of Laboratory Animal Practitioners; American College of Laboratory Animal Medicine; American Society of Primatologists; American Veterinary Medical Association; Commissioned Officers Association, USPHS; District of Columbia Veterinary Medical Association; National Capital Area Branch, American Association for Laboratory Animal Science; The Scientific Research Society of America; Association of Military Surgeons of the United States.

Honors and Awards: USPHS Distinguished Service Medal; USPHS Surgeon General's Exemplary Service Medal; USPHS Meritorious Service Medal; USPHS Commendation Medal; Department of Army Legion of Merit; Department of Army Meritorious Service Medal; Department of Army Commendation Medal; NIH Director's Award; Ohio State University College of Veterinary Medicine, Distinguished Alumnus Award; Oklahoma State University College of Veterinary Medicine, Distinguished Graduate Recognition Award; Selected for Federal Executive Institute Program; Alpha Zeta; Blue Key; included in 1973 Edition, American Men and Women of Science; Diplomate, American College of Laboratory Animal Medicine.

Publications: Author of one book and over 39 scientific papers.

ANIMAL RESEARCH

Senator HARKIN. Let me ask you about animal research here. That comes under your purview, right?

Dr. WHITNEY. Yes, sir; we support most of the animal resources.

Senator HARKIN. I was visited here a few weeks ago by Dr. Goodall, Jane Goodall. I have always had a lot of respect for her and her research into primates. But she has been involved in some ongoing discussions with NIH, has she not?

Dr. WHITNEY. Yes; she has.

Senator HARKIN. As I understand it, I hope I am not misinterpreting what she told me, but, her position is not that she is opposed to using animals for research, but it is the care and it is the social aspect of the animals, how they are kept and how they are taken care of that she was most concerned about. What have you done to answer some of her charges, especially in the use of the primates?

You know, another thing I just read in a book. I either read Science, Scientific American, or Discover, so I got it from one of those three. It said that 98 percent of our genetic make-up is the same as that of a chimpanzee.

Dr. WHITNEY. Yes, sir.

Senator HARKIN. That is pretty close.

Dr. WHITNEY. It is pretty close.

TREATMENT OF CHIMPANZEES

Senator HARKIN. And so, what have you done out there to, to answer some of her concerns about the use of chimpanzees and how they are treated and how they are kept for animal research.

Dr. WHITNEY. We have developed a number of breeding programs for chimpanzees in this country to preclude taking them from the wild. I believe that through these breeding programs, we will have sufficient numbers of chimpanzees to meet the biomedical research needs for the forseeable future. In developing those breeding programs, we used information from Jane Goodall and others to help us develop socialization strategies that will aid in resocializing animals that have come out of laboratory environments and to help us enhance the well-being and breeding capability of these animals.

We have done very well. Breeding age females from the 360 animals that were originally put into this program at the end of fiscal year 1986 have produced over 100 young chimpanzees. These chimpanzees are held in social groups; they are not held in isolation cages. One of Dr. Goodall's primary concerns was the isolation of chimpanzees. That is a problem we are addressing now.

Isolation of chimpanzees is generally not advisable, however, if you are working with an infectious agent like AIDS, it is very important to protect other chimpanzees and the people that work with the infected chimpanzees. It is a difficult situation to compromise. We are working very hard to make sure that chimpanzees are held in single cages for the shortest duration of time that is absolutely essential, and we are developing methods to provide them environmental enrichment.

Senator HARKIN. You utilize private businesses, do you not, to breed chimpanzees and keep them for you, things like that?

Dr. WHITNEY. No; they are not private businesses; they are all associated with nonprofit institutions. For example, Yerkes Primate Research Center at Emory University, New Mexico State University at Holloman Air Force Base, and the University of Southwestern Louisiana all have chimpanzee breeding colonies funded by NIH.

Senator HARKIN. But what I mean is, they are not entities that belong to you.

Dr. WHITNEY. No; we do not have an intramural breeding program; it is a cooperative agreement with extramural facilities.

Senator HARKIN. Do you specify to them, as part of your contractual agreement with them, that they have to meet these certain——

Dr. WHITNEY. Absolutely. In fact, during the competition for these cooperative agreements, a large portion of the scientific review included how the applicants intend to house and socialize these chimpanzees.

NEW ANIMAL WELFARE REGULATIONS

Senator HARKIN. All of the reports, I understand all three parts of the proposed standards for the psychological well-being of laboratory animals have been issued and that part 3 of those standards will require a doubling of the space available for primates and dogs.

The committee has been told that it would cost approximately $1 billion to implement this standard in all the various private-sector institutions, and just under $500 million in additional costs for improvement and expansion of Government facilities. Where did we get those figures? From you?

Dr. WHITNEY. No; those estimates are from the U.S. Department of Agriculture [USDA]. When the USDA was asked for an economic impact of the proposed regulations, their economists put together that figure of $1 billion for the extramural community. An interagency committee formed from Government agencies sponsoring animal research put together the figures for the intramural Government research cost.

We do know that between $60 million and $70 million will be required for the primate centers alone to meet the proposed part 3 regulations of the USDA.

Senator HARKIN. Well, I mean, are you, when do those have to be implemented?

Dr. WHITNEY. There was a 180-day comment period on part 3, which is the most expensive portion of the proposed regulations, and no implementation time has been given at this point. The proposed regulations will be looked at again after public comments are received.

ACCREDITATION OF NIH ANIMAL FACILITIES

Senator HARKIN. How much, beyond currently available funds, how much is needed at NIH to meet all the laboratory animal accreditation standards? I understand you have about $23 million available from previous appropriations.

Dr. WHITNEY. That is correct. Dr. Wyngaarden, would you like to answer that?

Dr. WYNGAARDEN. Our present estimate is that, over and above that, we need somewhere in the neighborhood of $25 million to bring all NIH intramural facilities up to AALAC accreditation.

Senator HARKIN. Is there anything in the budget on that?

Dr. WYNGAARDEN. There is nothing in the President's budget. During the House hearings before the Appropriation Subcommittee on Labor, HHS, and Education, we were asked by Chairman Natcher what we would do with $500 million in additional dollars and in that exercise we did put in funds for intramural facilities. But there is nothing in the President's budget.

Senator HARKIN. But it is supposed to be done, that you have to meet this requirement?

Dr. WYNGAARDEN. We want to very much and in fact, I made the decision 4 or 5 years ago that we set a 3-year target to bring the intramural animal facilities up to AALAC accreditation. We have already passed that target date and we would like very much in fiscal year 1990 to bring our facilities up to this standard. Additionally, we are in a somewhat awkward position of insisting on performance in the extramural community, when we are not yet meeting it ourselves.

Senator HARKIN. How much would you need in 1990; $25 million?

Dr. WYNGAARDEN. Yes; $25 million is the most recent figure.

Senator HARKIN. If you have anything different than that, let me know.

Dr. WYNGAARDEN. That $25 million is a very close figure. The exact figure is $23.5 million.

Senator HARKIN. Then how long, if you have got that money, then how long would it take to bring them up to standard, do you have any idea?

Dr. WYNGAARDEN. Well, it could probably be done or nearly done during fiscal yer 1990.

Senator HARKIN. It could be done?

Dr. WYNGAARDEN. Yes; it might run over just a little, but I think we could do most of it in fiscal year 1990.

ELIMINATION OF BIOMEDICAL RESEARCH SUPPORT FORMULA GRANT

Senator HARKIN. The fiscal year 1990 budget proposes elimination of the biomedical research support formula grants, funded this year at approximately $54.4 million. Approximately 635 grants are expected to be made in fiscal year 1989 to institutions which receive at least three NIH grants. This money is available for a broad range of purposes to support research infrastructure at universities.

I understand that NIH has proposed elimination of this program before, but that Congress has refused to go along. What arguments do you have to support the elimination of these biomedical research support formula grants?

Dr. WHITNEY. I think it is a matter of priorities, in terms of the research project grant having the higher priority. To stay within

the budgetary limitations, we found it necessary to eliminate this program. Do you want to speak to that, Dr. Wyngaarden?

Dr. WYNGAARDEN. I think that is exactly right. This amount of money represents 200, maybe 250 research project grants. In the President's budget, with a 2.3 percent over all increase, we would have fallen so far down in the number of research projects we could support, we thought that funding those was a higher priority than the BRSG, as valuable as they are.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. I will wait and see what I hear from my colleagues on that one. We will submit the balance of the record questions to you.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

BIOMEDICAL RESEARCH SUPPORT FORMULA GRANTS

Question. The FY 1990 Budget proposes elimination of the Biomedical Research Support (BRS) Formula Grants which were funded in FY 1989 at approximately $54.4 million. Approximately 635 BRS grants are expected to be made in FY 1989 to institutions which receive at lease 3 NIH grants. This money is available for a broad range of purposes to support research infrastructure at universities. I understand that NIH has proposed elimination of this program before, but that the Congress has refused to go along. What arguments can be made to support the elimination of these Biomedical Research Support Formula Grants?

Answer. In view of the continuing emphasis on investigator-initiated research as the most appropriate form of support, the BRSG activity is of a lower priority when compared to other programs that permit the directing of research funds to specific target areas.

REORGANIZATION PROPOSAL

Question. NIH has proposed to consolidate the Division of Research Resources and the Division of Research Services into one organizational component. The Division of Research Services, currently in the Office of the Director, has as it's primary mission the support of intramural, or on-campus research activities, and the Division of Research Resources has as it's primary mission the general support of research activities at off-campus institutions. I noticed that there is no budgetary or FTE position savings resulting from this reorganization proposal. What is the logic for this reorganization if NIH is not achieving any additional efficiencies?

Answer. When looking at the mission of the Division of Research Resources and the Division of Research Services there seems to be an overlap. One is concerned with intramural research support and the other with extramural research support. This consolidation is intended to increase the efficiency and improve the performance of programs that enhance and facilitate research. This merger will enable the NIH to position these programs and make the most effective use of staff. Through attrition we expect to combine duplicate positions, thereby achieving economics of personnel and, more importantly, effective integration. As a consequence, the new organization will provide enhanced support to both the intramural and extramural NIH community.

ACCREDITATION OF NIH ANIMAL LABORATORY FACILITIES

Question. I understand NIH has approximately $23 million available from previous appropriations to improve NIH animal facilities to meet the standards established by the American Association for the Accreditation of Laboratory Animal Care.

Beyond currently available funds, how much is needed at NIH in order to meet all laboratory animal accreditation standards?

Answer. NIH currently has $23 million available for renovations of intramural animal facilities. We estimate an additional $23.5 million will be needed to complete the renovations and enable all NIH animal facilities to receive American Association of Laboratory Animal Care accreditation.

PSYCHOLOGICAL WELL-BEING OF ANIMALS

Question. I understand that all three parts of the proposed standards for the psychological well-being of laboratory animals have been issued and that Part Three of those standards would require a doubling of the space available for primates and dogs. The Committee has been told that it would cost approximately $1 billion to implement this standard in all the various private sector institutions and just under $500 million in additional cost for improvement and expansion of government facilities.

What is the status of the standards for the psychological well-being of animals and does NIH support the standards, particularly Part Three? Also, what additional costs would NIH need to expend to meet the proposed Part Three standards for space for primates and dogs?

Answer. The status of standards for the psychological well-being (PWB) of laboratory animals particularly dogs and nonhuman primates is being addressed by the NIH. The NIH is currently supporting research which we believe will result in scientific data for improvement of the PWB of laboratory animals. However, the NIH does not endorse all of the standards as proposed in Part Three of the proposed regulations. There are numerous concerns regarding the actual implementation of these requirements. The NIH proposes that Part Three be reassessed and rewritten to more appropriately reflect general standards and minimal requirements.

The proposed Part Three standards would require upgrading of many existing facilities. Final cost estimates have not been determined as yet for the NIH intramural and extramural facilities. However, the USDA has estimated that Part Three of the new regulations will cost the research institutions about $111 million in capital expenditures for primate facilities and $138 million for dog facilities. These estimates are considered by many institutional officials to be extremely conservative. Space expansion and/or modifications, as well as equipment required for primates will necessitate much larger capital outlays. Virtually all existing cage systems will have to be replaced or modified to meet the proposed Part Three standards. In addition, the primate holding capacity of existing systems would be reduced by approximately 50 percent. Therefore, large expenditures would be required for new construction to accommodate for this loss of primate holding space.

ALTERNATIVE TO ANIMALS IN RESEARCH

Question. One of the primary NIH activities exploring the alternatives to using animals in research is the Biomedical Models and Materials Research Program funded in the Division of Research Resources. This program is funded in two mechanisms -- under the

centers program and with the smaller grants for developmental research under the other research category. Both of these areas have been proposed for reduction.

Are these reductions consistent with the NIH interest and the Committee's interest in further expansions of developing alternatives to animals in research?

Answer. In order to continue to fund an adequate number of investigator-initiated research project grants, NIH policy was to reduce other mechanisms slightly from the FY 1989 level.

BIOMEDICAL RESEARCH SUPPORT FORMULA GRANTS

Question. The Division of Research Resources (DRR) budget justifications proposes elimination of the Biomedical Research Support formula grant activity, a decrease of 53.8 million dollars. This funding reduction was deemed necessary in order to attain the goals of the Balance Budget and Emergency Deficit Control Act of 1989. Why was this portion of the program targeted alone rather than equal across-the-board cuts including both the Minority High School Student Research Apprentice Program and the Shared Instrumentation Grants Program? How many grantee institutions will lose their awards as a result of this funding cut?

Answer. During the formulation of 1990 President's Budget, it was determined that the Biomedical Research Support Grant Formula Program was necessarily of a lower priority then either of the Minority High School Student Research Apprentice Program, which focuses on increasing the numbers of minorities involved in biomedical research, or the Shared Instrumentation Grant Program, which is focused on addressing critical shortages in research instrumentation.

In FY 1989, 633 institutions received Biomedical Research Support Grants. Under the proposed FY 1990 budget no institutions will receive Biomedical Research Support Grants.

NATIONAL CHIMPANZEE MANAGEMENT PLAN

Question. Congress has received an enormous amount of mail concerning the National Chimpanzee Management Plan. Most of the letters asked that funding for this program be stopped. The original goal of the plan was to produce and raise 60 chimps a year for future research and breeding. Is it envisioned that this plan will be supported indefinitely or is it only supposed to exist for a finite number of years?

Answer. The National Chimpanzee Management Plan (NCMP) was initiated in 1986 by the Division of Research Resources. The purpose was to make the chimpanzee breeding resources self-sustaining and to provide the chimpanzees necessary for certain types of biomedical research and testing, such as AIDS and viral hepatitis. The program also supports research on chimpanzee health and well-being, genetics, reproduction, and environmental enrichment.

It is anticipated that the NCMP will be continued, although it is presently funded through September 1990.

REGIONAL PRIMATE RESEARCH CENTERS

Question. The primate centers have been the recipient of large sums of money to fund numerous projects related to AIDS investigations. Who makes the decisions on how this money is allocated? Do the directors of the centers have the discretion to apply AIDS funding to such activities as facility expansion and renovation?

Answer. During the past several years, the seven regional primate research centers have received a number of resource and research awards related to AIDS investigations. These awards from DRR and several of the NIH categorical institutes have resulted from applications which underwent peer-review for scientific merit. All allocations of funds for these awards are made in strict accordance with recommendations from the peer-review process. Within these constraints, the directors of the primate research centers supervise the use of funds related to these activities. Reprogramming of funds from other categories into facility expansion and renovation would require prior approval from the awarding agency.

Some of the AIDS-related funds have been specifically directed by the funding agencies for the expansion of nonhuman primate resources and for facility renovations required to accomplish this type of research. This includes funds needed for the appropriate housing of research animals, proper biocontainment conditions and for environmental enhancement. For example, the Division of Research Resources has funded the Research Facilities Improvement program for these purposes.

SHARED INSTRUMENT GRANTS

Question. The shared instrument grants program provides investigators access to grants to obtain very expensive scientific equipment. The number of applications for these grants tripled from 1984 to 1988. The ceiling for the 1989 awards was raised from $300,000 to $400,000. Will there be a need to raise the ceiling even higher in the near future?

Answer. The Division of Research Resources is currently evaluating the costs and types of big-ticket items requested and the effect raising the ceiling would have on the award rate. It would appear that the $400,000 ceiling is reasonable for the next year or two.

NEW ANIMAL WELFARE REGULATIONS

Question. Sometime in 1989 the Department of Agriculture will be issuing new animal welfare regulations called for by enactment of the Animal Welfare Act of 1985 (P.L. 99-198). A section of the law calls for the Secretary (Agriculture) to promulgate rules to create a physical environment adequate to promote the psychological well-being of (non-human) primates. What actions will NIH supported research facilities, where non-human primates are housed, have to undertake to provide for such conditions? What will constitute the

psychological well-being of a primate? Will this require costly renovations? Has DRR made any evaluation of what it might cost to be in compliance with the wording of this law and the forthcoming regulations?

Answer. NIH's present approach is to enrich the environment of nonhuman primates by using currently available methods. A plan to promote psychological well-being (PWB) has been drafted by the Office of Animal Care and Use, NIH. PWB is not a well defined term and what actually constitutes PWB of a primate is not known. It could be additional space, play toys, mirrors, access to outside areas, music, or any of a number of other factors. However, there is no actual scientific evidence to demonstrate that doubling the space will result in an enriched environment. It will take many years of concerted effort to determine the most appropriate methods of enriching the environment of the various species of nonhuman primates and dogs used in biomedical research. The draft regulations published by the U.S. Department of Agriculture to promote PWB of non-human primates and dogs has been estimated to cost animal facilities approximately $1 billion, with at least one half of that amount needed for new equipment.

Question. Animal rights advocates keep arguing that government agencies are not providing enough incentives to promote the use of alternatives to replace animal models currently used for research and testing. Legislation, pending in Congress, calls for elimination of historic tests such as the rabbit eye irritancy and the classical lethal dose-50 test. At the present time, can scientists and toxicologists forego the use of these tests, and use some type of accurate and validated substitute that would provide better data than that derived from the older tests?

Answer. The argument by animal rights activists that there are not adequate incentives promoting the use of alternatives to current research models is not only incorrect, but also misleading. At the core of biomedical research is the constant search for better ways to understand the human body, and protect and improve human health. Driven by scientific as well as practical considerations, quicker, less expensive and more effective methods are continually evolving. These new methods are routinely and widely shared among researchers, regulators and others in order to assess their potential and, as appropriate, to encourage their use.

Some of these innovative methods, which have resulted from advances in the science base, may involve either the elimination of animal models, reduction in numbers used, or improvement in animal care.

Currently there appear to be some promising alternatives to the Draize being developed. It is our understanding that these still need to be validated fully -- that is that they measure what they are intended to measure, that results are consistent with current methods, and that they are reproducible among laboratories. With regard to the classical LD-50 test, it can usually be replaced by other methods. However, there are still certain instances in which there is need for acute dose toxicity data; for example: determining the precise therapeutic margin of a highly toxic drug like digitalis, accurately evaluating the toxicity of an agent that

shows promise for preventing cancer, designing effective antidotes, and establishing the effective dose of a selective poison for vermin.

NIH funded research in molecular and cell biology is the principle national investment in creating the knowledge base from which research and development on alternatives can take off. While there are some promising advances being made in the development and validation of non-animal methods, whole animal models -- today and into the foreseeable future -- will continue to be essential to maintaining progress in biomedical research.

ACCREDITATION OF ANIMAL FACILITIES

Question. DRR reported last year that 565 research facilities, which are eligible to receive Public Health Service support, are not accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC). It was also stated that these facilities were in full compliance with the "PHS Guide for the Care and Use of Laboratory Animals" or were actively planning to upgrade their facilities. What percentage of these facilities were site-visited in 1988 to determine if they were actually in compliance with PHS policy? Have any of these facilities become AAALAC accredited in the past year?

Answer. The Office of Protection from Research Risks (OPRR), NIH exercises oversight responsibility for the approximately 800 domestic institutions receiving PHS support for research involving animals.

Compliance oversight for the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy) is based on a wide variety of regulatory methods including review and approval of Assurances, reports from institutions certifying that the required internal semi-annual inspections of animal facilities and evaluations of programs have been conducted, review of research protocols by Institutional Animal Care and Use Committees, requirements for prompt reporting of serious non-compliance with the PHS Policy or Guide, evaluation of allegations of non-compliance with the PHS Policy, the conduct of special reviews or site visits to selected institutions, and a nationwide education program. Evaluations and investigations are also conducted through means other than site visits such as specific written inquiries, requirements for documentation, verification, and additional internal investigation and reporting requirements. Experience has demonstrated that this multifaceted approach to regulation has been far more cost-effective that reliance on any single method.

The Assurance of Compliance (Assurance) with PHS Policy is a mechanism through which all institutions receiving PHS support for activities involving animals certify that they are operating in accordance with the PHS policy and the Guide for the Care and Use of Laboratory Animals (Guide). The Assurance provides detailed information on how an institution implements the requirements. Accreditation by the AAALAC is recognized by OPRR as evidence of a sound program of animal care and use, however, it is a voluntary

program and not required as part of the Assurance. The Assurances and other compliance mechanisms are utilized for all PHS supported institutions, regardless of AAALAC status.

Keeping in mind that site visits are not intended to be used by OPRR as the primary means of regulatory oversight for the PHS Policy, approximately two percent of the non-AAALAC accredited PHS supported institutions were site visited in 1988 as part of NIH compliance oversight programs.

During the calendar year 1988, nine PHS supported institutions gained full accreditation by AAALAC.

REORGANIZATION PROPOSAL

Question. Please describe the benefits of the merger of this Division with the intramural Division of Research Services. Do you foresee any increases in cost resulting from the merger? Will there be any negative impact on staff?

Answer. As now envisioned, there will be no increased cost resulting from the merger. In fact, through attrition we anticipate a slight reduction in staff required to manage these two organizational components which may reduce costs.

No negative personnel impacts are foreseen as a result of this merger. Personnel will be absorbed within the enlarged organization with no adverse impact on grade.

MINORITY PROGRAMS

Question. How will the Division of Research Resources continue its historic presence in the area of support of minority programs after the Minority Biomedical Research Support program is transferred out of the Division?

Answer. DRR will continue to administer the Research Centers in Minority Institutions program. This program, appropriated to the Director, NIH, has been administered in DRR since its inception. Furthermore, the Director, NIH, is recommending the transfer of that program to the appropriation for Research Resources.

In addition, DRR will continue to administer the Minority High School Student Research Apprentice Program, the only program at NIH uniquely designed to attract high school students to careers in biomedical research.

MINORITY HIGH SCHOOL STUDENT RESEARCH APPRENTICE PROGRAM

Question. How many students will we support in the Minority High School Student Summer Research Apprentice program in 1989? In 1990? Does the budget support all of the High School Students who want to participate? If not, how many more do you think we could support?

Answer. In FY 1989, the Minority High School Student Research Apprentice Program will support 1,116 summer students at 348 institutions across the country. This is the same number of students we supported in FY 1988, however, 25 more schools will participate in FY 1989. The FY 1990 request level of $1,710,000 will support 24 more students than in FY 1989.

Currently only about half of the schools eligible for the Minority High School Student Research Apprentice Program request support for students. At the participating institutions, there is keen competition for the student slots. We estimate that there are eight high-ability high school students for each NIH apprentice chosen. Without increasing the number of applicant institutions we estimate 4,000 highly qualified students could be supported by this program in FY 1990.

RESEARCH FACILITIES IMPROVEMENT GRANTS

Question. How many applications for the Research Facilities Improvement Program grants did you receive, and how much did they request? How many applications were approved but not funded? How much would it take to fund those applications?

Answer. The Research Facilities Improvement Program received 115 applications for AIDS Infrastructure grants requesting over $94 million. Sixty-two grants were recommended for support at a level of approximately $37 million but will not be funded. These fell into two groups, one group of 23 high merit applications would require an additional $14 million to fund, and the other group of 39 grants were approved at a recommended level of $22 million and were less meritorious but still worthy of support.

PRIMATE RESEARCH CENTERS RENOVATIONS

Question. In your professional judgment, how much is needed to meet the Primate Centers' ongoing repair and renovation needs, excluding those related to new regulatory requirements? Can you estimate the costs to the Primate Centers of complying with the new USDA requirements? Can you estimate the costs for all the other institutions using animals for NIH projects?

Answer. Excluding the new USDA requirements, it is estimated that a minimum of $3 million per year--with annual inflation increases--will be required on a continuous basis by the seven centers to properly maintain their physical facilities. This estimate does not include renovations and equipment for AIDS-related resource and research activities. The centers are now approximately 30 years old and are in constant need of repairs due to heavy use over the years.

An evaluation of these needs is currently in progress. Preliminary estimates which are considered very conservative, indicate that at least $70 million of initial capital expenditures will be required by the seven centers to achieve full compliance with these new regulations, but, as of yet, we do not have firm estimates. The USDA has estimated that Part Three of the new regulations will cost all research institutions about $111 million in capital expenditures for primate facilities and $138 million for

dog facilities. These estimates are considered by many institutional officials to be extremely conservative. We hope to have much firmer cost estimates within the next several months.

BIOMEDICAL RESEARCH SUPPORT FORMULA GRANT

Question. NIH is requesting no funds for the Biomedical Research Support Grants. Why is this program given such a low priority despite the fact that we hear from Institutions across the country that this is one of the most valuable NIH program? What, in your professional judgement, is the appropriate level for this program?

Answer. In developing the 1990 budget, the NIH policy was to award the highest priority to investigator-initiated Rearch Project Grants. The BRSG program was awarded a lower priority in order to permit NIH to support an adequate number of investigator-initiated research project grants. Maintenance of a solid base of investigator-initiated research project grants will ensure that researchers with meritorious new ideas will have an opportunity for successfully competing for funds. In my professional judgement, the appropriate level for this program in FY 1990 is $90 million.

SHARED INSTRUMENTATION GRANT PROGRAM

Question. What is the objective of the Shared Instrumentation Grant (SIG) program? Is the SIG program meeting its objective? How many applications did you receive for these grants in 1988 and 1989? Can you explain the increase in requests?

Answer. The objective of the Shared Instrumentation Grant (SIG) is to make available, to institutions with a high concentration of PHS-supported investigators, expensive research instruments on a shared use basis. Since its inception in 1982, the program has made over 1,000 awards for high cost instrumentation to over 325 institutions across the country.

In its 8 years of operation, the program has witnessed a continued increase in requests from the biomedical community. In FY 1988, the program received 281 applications requesting $64,600,000. In FY 1989, 407 applications requesting $103,200,000 were received, this is a 45 percent increase over FY 1988. This increase in applications continues in FY 1990 with over 400 applications received requesting over $108,000,000.

The rapid technological change in biomedical research instrumentation and the opening up of new research areas are among the reasons for this increased number of applications. In the last 5 years, SIG awards for instruments for automated microchemical equipment--protein sequencer, peptide synthesizers and DNA sequencer--reflects the rapid emergence in the bioscience of protein and gene engineering. Strong interest has also been shown in new instruments such as adherent cell sorters and confocal microscopes. Another notable shift is that higher power NMR spectrometers are being requested. Many of these may be replacing obsolescent equipment.

QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

PRIMATE RESEARCH CENTERS RENOVATIONS

Question. The DRR's budget justification indicates that $3 million has been set aside from within the funds available to the Primate Centers to carry out repair and renovation of the Centers in order to maintain standards for accreditation by the American Association for Accreditation of Laboratory Animal Care. Maintaining and improving these facilities in order to ensure the humane treatment of primates is a Congressional priority and one which I share. With the budget for this activity frozen at last year's level, will the Centers be able to comply fully with these standards? What was the DRR's original request to the NIH for this activity?

Answer. Funds have been made available for repairs of facilities and replacement of obsolete equipment at the seven Regional Primate Research Centers since 1984. The center's facilities are now approximately 30 years old and major repairs and renovations are constantly needed to properly maintain them. Approximately $15.2 million has been made available for this purpose since 1984 and many of the major facility deficiencies at the seven centers have been addressed.

DRR's original request to NIH was $3 million to continue these activities. If the current level of $3 million per year for this purpose is sustained with inflation increases over future years, it appears adequate to provide for most general repairs and replacement of obsolete equipment at the seven centers.

CORE SUPPORT TO THE PRIMATE RESEARCH CENTERS

Question. The FY'90 budget request for Primate Centers is $313,000 below the level appropriated in FY'89. With the research activity at the Centers increasing, how can they be expected to maintain the current level of services when their operational budgets are being reduced? For FY'89 what funding recommendation did the Centers receive through the NIH peer review process? What level was ultimately provided? How does this ratio compare with the previous four fiscal years? What was the DRR's original request to the NIH for Primate Centers?

Answer. Decreases in funding in the FY 1989 and FY 1990 budgets for core functions of the Regional Primate Research Centers concern staff at all seven centers. There will likely be a slowing down of some of the research activities. The total core support recommended in FY 1989, through the NIH peer review process, for the seven Primate Research Centers was over $35 million.

In FY 1990, $22.515 million is requested for core support of the primate research centers exclusive of repairs and renovations. This compares to $22.828 million in FY 1989, $23.705 million in FY 1988 and $22.044 million in FY 1987. DRR's original request to NIH for core support for the primate research centers exclusive of repair and renovation funds was $26.684 million.

PRIMATE RESEARCH CENTERS CONVERSION FOR AIDS RESEARCH

Question. To what extent do the Primate Centers report the dislocation of essential programs and Center functions as a result of the rapid conversion to research related to AIDS? How much would be necessary to restore the Centers' dislocated facilities?

Answer. All of the Primate Research Centers are engaged in critical AIDS-related research and resource activities. Their rapid conversion of programs during the past several years to meet this national emergency has reduced their space and other resources available for other important types of investigations on human health problems. The centers have converted approximately 35,000 square feet of their existing laboratory space and biohazard containment facilities for animals and research needed for these newly initiated AIDS programs. Additional space and other resources needed to replace those now converted to AIDS activities at all seven centers are estimated to cost about $32 million.

NATIONAL CENTER FOR NURSING RESEARCH

STATEMENT OF DR. ADA SUE HINSHAW, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Let us go now to the National Center for Nursing Research. Dr. Hinshaw.

Dr. HINSHAW. Thank you, Senator Harkin. It is both a privilege and a welcome opportunity to address you today. I would like to discuss the programs and the initiatives of the National Center for Nursing Research.

We are pleased to share several promising research developments already evident in the very short history—less than 3 years—of the National Center. First of all, a major target of nursing investigations is the effectiveness of nursing procedures routinely performed for acutely ill patients. The NCNR is supporting a series of studies related to endotracheal suctioning of critically ill adults and newborns.

ENDOTRACHEAL SUCTIONING

Endotracheal suctioning involves inserting a tube into the trachea, or windpipe, to remove secretions which the patient is unable to remove normally. In the process, the oxygen flow to the individual is also reduced. In acutely ill patients, such a loss of oxygen can be harmful. These studies are testing ways to perform this procedure which will reinforce the oxygen supply and result in as little disturbance to breathing as possible. Findings from the research will contribute to the development of suctioning procedures which are less damaging to critically ill patients.

LOW BIRTH WEIGHT INFANTS

Low birth weight infants are another major concern of nursing practice. NCNR supports research to reduce infant mortality through better nursing techniques which help maintain or improve the mother's health during pregnancy and provide optimum care to the preterm and low birth weight infant.

Current methods of caring for these high-risk infants in the neonatal intensive care units need to be continually evaluated and, as warranted, new methods of care instituted. For example, many preterm infants, too weak to take a bottle, are fed through a tube into the stomach, in a method called gavage feeding. This can continue for days or weeks before oral feeding can be successfully started.

NCNR grantees are studying how oral feeding can be successfully introduced to promote the most rapid development of the newborn. A special bottle-feeding routine resembling breast-feeding has

been devised to allow the infant some self-regulation in sucking. Early results suggest that the infants receiving this self-regulating bottle protocol slept easier after the feeding, were less restless, cried less often, and most importantly, had weight gains almost three times as great as other infants not on this protocol.

RESEARCH ON THE BURDEN OF CARE

Congress recommended that NCNR and the National Institute on Aging develop a special program in burden-of-care research, particularly for individuals and families faced with Alzheimer's disease or related disorders. The complexities and problems of the informal caregiving rendered by families must be understood and information provided to maintain the health of the caregivers, and to take care of their frustrations and concerns, as well as enhance patient recovery.

NCNR investigators are studying ways to teach caregiving skills, the effectiveness of community-based social support and services that link informal and formal caregiving, and the morbidity and mortality risks that may be associated with family caregiving. New projects will be initiated in fiscal year 1989 to determine the relationship of caregivers' perceived and objective stress response to change in the activities of patients with mental deterioration or dementia.

Several other initiatives have been undertaken that I will simply summarize. A new centers program has been developed in 1989, there is a rapidly developing national nursing research agenda for nursing research priorities, the research training objectives for nurse scientists are moving forward, minority initiatives for research and research training are underway, and the development of a collaborative intramural research program has begun.

PREPARED STATEMENT

Mr. Chairman, the fiscal year 1990 budget request for the National Center for Nursing Research is $29,970,000. That is an increase of 5.4 percent. I would be pleased to answer any questions.

[The statement follows:]

STATEMENT OF DR. ADA SUE HINSHAW

Mr. Chairman, it is both a privilege and welcome opportunity to address you today. I would like to discuss the programs and initiatives of the National Center for Nursing Research (NCNR).

We are pleased to share several promising research developments already evident in the very short history--less than three years--of the National Center for Nursing Research. The ultimate purpose of nursing research is to provide relevant, reliable information which can be used in nursing practice to improve health care. Nursing research systematically examines human biology and behavior involved in promoting health, preventing disease, providing care to individuals and families with acute and chronic illnesses, and understanding the effects of environmental influences on health and illness. A major objective of such research is to select particular actions of nurses that are most successful in lessening the effects of illness and helping individuals and their families cope with health problems, regardless of the setting--hospital, community agency, nursing home, or home.

A major target of nursing investigations is the effectiveness of nursing procedures routinely performed for acutely ill patients. The NCNR is supporting a series of studies related to endotracheal suctioning of critically ill adults and newborns. Endotracheal suctioning involves inserting a tube into the trachea (windpipe) to remove secretions which the patient is unable to take care of normally. In the process, the oxygen flow to the individual is also reduced. In acutely ill patients, such a loss of oxygen can be harmful. These studies test ways to perform this procedure which will reinforce the oxygen supply and result in as little disturbance to breathing as possible. Findings from this research will contribute to the development of suctioning procedures which are less damaging to critically ill patients.

Low birthweight infants are another major concern of nursing practice. NCNR supports research to reduce infant mortality through better nursing techniques which help maintain or improve the mother's health during pregnancy, provide optimum care to the preterm and low birthweight infant, and assist the formation of a positive maternal infant attachment. Current methods of caring for these high risk infants in neonatal intensive care nurseries need to be continually evaluated, and as warranted new methods of care instituted. For example, many preterm infants, too weak to take a bottle, are fed through a tube into the stomach (gavage feeding) for days or weeks before oral feeding can be successfully started. NCNR grantees are studying how oral feeding can be safely introduced to promote the most rapid development of the newborn. A special bottle feeding routine resembling breast feeding has been devised to allow the infant some self regulation in sucking. Infants receiving this self regulating bottle protocol slept easier after the feeding, were less restless, cried less often, and most importantly had weight gains almost three times as great as other infants not on the protocol.

We also need to develop selective nursing interventions for monitoring low birthweight infants after discharge so as to maintain the functional levels that they achieved while in the hospital. One study concludes that early hospital discharge of

very low birthweight infants who meet certain criteria, coupled with counseling of the parents and home care follow-up by nurse specialists, improves the infant's environment, is safe, effective, and saves approximately $18,560 per infant in hospital and physician costs.

The NCNR is committed to the conduct and support of clinical research which focuses on the physical, psychosocial, and ethical problems central to the nursing care of HIV-infected patients, their partners and families. The Center for Disease Control estimates, derived from 1988 statistics, indicate that between 1 million and 1.5 million Americans are now infected. Much of the care provided to people with AIDS related illness takes place in the home, either in the form of self-care or by friends, relatives and community based nurses. To help meet the demand for information and services relating to home care, a network called "ComputerLink" is being developed and tested.

ComputerLink will be part of an existing community computer system and provide general information about HIV infection as well as answer questions about the associated care problems. Participants in the study will be provided with computer terminals linked to the network and taught how to use them. One feature of the network will help users analyze and make decisions about the complex problems often associated with home care for HIV infection. The network will provide a link not only with professional health care providers, but also with peers, thereby potentially helping to combat the problem of social isolation among patients and their partners. The prevention of AIDS transmission and the care of patients, partners and families experiencing this condition will continue to be given high priority.

Congress recommended that NCNR and the National Institute on Aging (NIA) develop a special program in burden-of-care research, particularly for individuals and families faced with Alzheimer's disease or related disorders. The complexities and problems of the informal caregiving rendered by families must be understood and information provided to maintain the health of the caregiver, ameliorate their frustrations and concerns as well as enhance patient recovery. NCNR investigators are studying ways to teach caregiving skills, the effectiveness of community based social supports/services that link informal and formal caregiving, and the morbidity and mortality risks associated with caregiving. New projects will be initiated in FY 89 to determine the relationship of caregiver's perceived and objective stress response to changes in the activities of daily living of patients with mental deterioration (dementia) and the use of community agencies and support groups. In addition, investigations will identify caregiving variables which predict institutional placement of the patient with dementia.

More studies of the long-term care of the frail elderly are needed. We must develop and test strategies for maintaining independence as well as improving wellness and quality of life specifically for individuals in nursing homes and community-based settings. The U.S. Census Bureau has estimated that there are more than three million elders over 85 years of age as of 1988. It is estimated that by the year 2010, this group will increase 115 percent and number 6.5 million. Deficits in strength, mobil-

ity and balance pose major problems for many older individuals. When these physical deficits are combined with undesirable social or environmental conditions, the risk for injury rises. The NCNR is working closely with NIA to encourage studies to prevent injuries in older persons, test interventions to improve physical capabilities, make living environments safer, and help older people adjust to declining physical capacities. Studies are under way that examine adaptation, hardiness, and self-care of individuals with chronic illnesses--diabetes mellitus, cancer, and arthritis--in order to identify strategies that will help individuals adapt to their illness and avoid complications.

In FY 1988 NCNR initiated a program to study the retention of nurses and the environments that enhance the delivery of quality nursing care. The nursing community shares society's concern about retaining nurses within acute care settings. The studies, supported cooperatively with the Division of Nursing at the Health Resources and Services Administration, deliberately focus on the outcomes for patients when the hospital environment is reconstructed to promote nurses' ability to give professional, quality care. Among the environmental factors studied are case management of patient care and new ways of organizing care to be more efficient and effective. Studies have shown that, under certain circumstances, nursing interventions have shortened the length of time patients require hospitalization, decreased harmful consequences from specific medical treatments, and increased the level of patient satisfaction.

Several initiatives established by the NCNR have been successful in providing leadership for the nursing research community. First, the National Nursing Research Agenda (NNRA), outlining the major priorities for nursing research was established to promote greater depth in the knowledge base for nursing practice. The NNRA consists of seven priority areas: Low Birthweight: Mothers and Infants, HIV Infection: Prevention and Care, Long Term Care for the Elderly, Symptom Management, Information Systems, Health Promotion, and Technology Dependency Across the Lifespan. The development of the agenda is proceeding on schedule with five priority areas being refined. Two priorities (Low Birthweight and HIV Infection) will be completed and guide NCNR research programs in FY 1990. The nursing community and the National Advisory Council for Nursing Research are heavily involved in the development of this research plan and have applauded the NCNR for the evolution of the NNRA.

Second, the NCNR research training initiative is based on the National Academy of Science projections of the national need for biomedical and behavioral personnel for nursing research. The initiative consists of three components: 1) establishment of a research career trajectory, 2) substantially increasing the total number of fellows and trainees, and 3) significantly increasing the number of nurses in postdoctoral training. The nursing scientific community has been excited about the establishment of a career trajectory with awards for research training and career development made available for early, mid-stage, and senior scientist levels. This will allow nurse investigators to stay on the "cutting edge of science" during their entire scholarly career and promote excellence in the evolving nursing knowledge base. The total number of research training and career development

awards was substantially increased from 165 in FY 1987 to 191 in FY 1988. The total is expected to increase to 225 in FY 1989. In addition, we are encouraged that the number of nurses in postdoctoral study has increased, and NCNR will continue to emphasize postdoctoral training.

Third, the NCNR initiative to attract minority nurses was launched during FY 1988. An ad hoc minority panel was convened to identify program needs and strategies to enhance minority nurse involvement in research and research training. All new institutional research training grants are now required to include a minority recruitment plan and directors of existing research training programs are encouraged to apply for additional trainee positions for minority nurses. The new specialized centers program requires a minority recruitment component as part of the core grant. NCNR is working with the Research Centers in Minority Institutions Program, Division of Research Resources, to encourage linkages with minority schools of nursing and minority nurses in research. Several important contacts for consultation and implementation of the minority initiatives have been made with the Black Nurses' Association, the Association of Black Nursing Faculty in Higher Education, and the Hispanic Nurses' Association.

Fourth, a Specialized and Exploratory Centers program has been started, and the initial awards will be made later this year. The program will focus resources on specific areas of care in research environments to enhance the depth of the knowledge base needed for nursing practice.

As a fifth initiative, I am delighted to report that a collaborative intramural program with the National Institute of Allergy and Infectious Diseases and the Department of Nursing at the Clinical Center has been started. This program will focus on nursing care problems with AIDS patients, their partners, and families. The ultimate goal of this effort is to provide information for practice which will minimize dysfunction and suffering due to physical or psychosocial sequallae of HIV infection, such as nutritional disorders, diarrhea, fatigue, lesions in the mouth, or dementia. While HIV infection remains incurable, it is important to direct efforts towards decreasing morbidity and increasing the individuals' ability to cope with symptoms from the disease in order to maximize the quality of life and diminish both economic and personal cost.

Mr. Chairman, the FY 1990 budget request for the National Center for Nursing Research is $29,970,000. I will be pleased to answer any questions you may have.

SELF-CARE HABITS OF THE ELDERLY

Senator HARKIN. Thank you very much, Dr. Hinshaw. I understand at the University of Iowa, there is an effort underway to study self-care habits of the elderly in four different cultures. What do you expect to learn from this and how do you hope to have the findings implemented to improve the self-care habits among the elderly? Do you know what that is all about?

Dr. HINSHAW. Yes; I do, sir. That particular study is looking at four different cultural patterns for how one institutes self-care and home remedies during illness. The four different cultures are European-Mediterranean cultures from which individuals have moved into Iowa. There is a cultural anthropologist nurse on the University of Iowa faculty who is proceeding with this study.

The four groups of elderly being studied are Norwegian, Czechoslovakian, Amish, and Greek. Among those four cultures, the subject of interest over time—it is a longitudinal study—is what self-care practices they use first when they are ill, what motivates them to institute certain home remedies, and at what point they decide to visit the clinics to seek what we would call western medicine in a cultural study.

This may help us to know not only when they will access western medical clinics and health care practice, but also, how we can help them to fit our recommendations for treatment and care into their cultural behaviors. This may concern their dietary patterns, their ways of taking care of each other, and other behaviors. There are a number of different issues that have to do primarily with compliance.

BEHAVIORAL RESEARCH

Senator HARKIN. Unlike most of the other institutes at NIH, approximately 70 percent of the grants awarded by the nursing center are for behavioral research, that the nursing center funds approximately 50 percent of the behavioral research done at NIH. Why is it such a large proportion in behavioral research?

Dr. HINSHAW. I am not sure of the statistics in terms of our percentage of the NIH total, however, 68 percent of the NCNR extramural budget in fiscal year 1988 supported health promotion and behavioral research. That clearly reflects the orientation of nursing to the more preventive, coping, caring aspects of health care.

Biomedical research focuses very well on the disease itself, treatment of the disease, and the pathologic mechanisms that we need to understand. Nursing research is interactive with and complementary to that, and focuses on caring for the individuals and families who are undergoing treatment and have to cope with the disease that are in place.

As a result, our orientation is toward behavioral research and health promotion.

PRIORITY AREAS FOR RESEARCH

Senator HARKIN. You have seven priorities, seven broad priority areas. I guess the two priorities established for fiscal year 1990 are

work on low birth weight infants, which you talked about, and the care of HIV patients. What are the other five priorities?

Dr. HINSHAW. The first of the other five priorities, three of which will be the focus of nursing research in 1991, is symptom assessment and management. It is often the nurses who are living with patients for 24 hours a day who really identify pain symptoms, fatigue, hunger, thirst, and many other kinds of symptoms. Knowing how to assess them and knowing how to provide the best care mechanisms for them is an important field of nursing research.

The second priority area is long-term care of the elderly, particularly elderly with chronic illness, which is often the case. Much of that work is already underway and is going to be coordinated with the National Institute on Aging. We are very careful about making that kind of collaborative arrangement when we have overlapping interests in our research programs.

The third area in 1991 will be information systems. In the priority area of information systems, we need to establish taxonomies, logical systems of labeling conditions and hospital care procedures; and we need to get these information systems into use in hospital care. The intent is to achieve greater effectiveness in care.

The next priority area is health promotion and self-care, in which we will be starting a large endeavor. The last priority area is technology dependency, particularly among the elderly. As people are sent home from the hospital with respirators and hyperalimentation feedings, reflecting the newest technology, it is hard for families to care for those individuals in the home, and increasingly difficult working with them in the hospitals.

NURSING SHORTAGE

Senator HARKIN. I have given many speeches in which I have talked about nursing being the most underutilized profession in our society. And I still believe that--that nurses are well-educated, well-trained, and then they are relegated to filling out a chart and taking temperatures.

As we move ahead in terms of long-term care and more preventative care, we should look more at preventative care, long-term health care of both the elderly and disabled people. It would seem to me that we are looking at people that can interact with elderly people, disabled people, over long periods of time; we can focus in this area.

You mentioned as one of your priorities long-term care; I would hope that that would be one of the highest priorities. In other words, how do you meld the nursing profession with the need for long-term care? How do you meld the nursing profession with the need for more preventative health care on a community basis?

We obviously have a nursing shortage in the United States, but I would think if people would see this as a career path, as someplace where they could develop skills, involved with the health community on, perhaps, a reimbursable basis, as physicians are, that it might encourage more people to take that up as a profession and be involved in community-based health care, long-term care, preventative care.

Dr. HINSHAW. That may very well come to pass. I think that one of the major things the Commission on Nursing found in terms of the nursing shortage—which is really a demand problem rather than a supply problem—was that, often, nurses are not utilized as professionals and, therefore——

Senator HARKIN. Underutilized.

Dr. HINSHAW. Exactly. They are not staying in the hospital settings, and not staying in nursing home settings because of this. I think if we can turn that around and begin to help them function in environments in ways which really utilize their scholarly background, that will make a difference in their retention as well. But there are several factors that could be addressed within that issue.

BEHAVIORAL RESEARCH

Dr. WYNGAARDEN. Mr. Chairman, with your permission, I would like to make a comment about the NIH budget on behavioral studies. We may be using definitions that are different from the ones that are in your figures, but we list a total of $233 million in health and behavioral studies within the fiscal year 1990 request of which 8 percent would be in the Nursing Center.

Incidentally, this amount for the 1990 request is three times as great as the 1983 figure. Our behavioral effort has increased from $79 million in 1983 to $233 million in 1990.

Senator HARKIN. How much of that is in the Nursing Center?

Dr. WYNGAARDEN. The figure I have is $18.9 million.

Senator HARKIN. About $18.9 million of $233 million.

Dr. HINSHAW. I believe that is correct.

Dr. WYNGAARDEN. Out of $233 million, it is about 8 percent.

Senator HARKIN. Where is the rest of it located?

Dr. WYNGAARDEN. About $61 million is in the Cancer Institute, $33 million in the Heart Institute, $15 million in NIDDK, $33 million in Child Health, $24 million in the Aging Institute, and about $20 million in DRR.

Senator HARKIN. So when I said that Nursing Center funds approximately 50 percent of the behavioral research done at NIH, that is way off.

Dr. WYNGAARDEN. By our definition, it would be 8 percent of the work in health and behavior. In cancer, for example, that would relate to all the modifications of smoking behavior that we are trying to introduce.

Dr. HINSHAW. Also, for example, in aging, they have a large endeavor in caregivers and issues of caregiving. We are active in that initiative with them. While a large part of our budget—66 percent in fiscal year 1990—is committed to behavioral research, we are still a very small part of NIH's budget—about one-half of 1 percent—although we support about 8 percent of all behavioral research at NIH.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. OK. Thanks for straightening that out. We will submit the balance of the questions to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Department for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

APPROVAL RATE

Question. When a grant first comes to NIH it is reviewed and over 90 percent of the grants are approved and are eligible for funding. I noticed that for the Nursing Center approximately 50 percent of the grants submitted for funding are approved as eligible for funding. Does this mean that you are getting a lower quality of application as compared to the other Institutes?

Answer. No, we do not feel that the National Center receives a poorer quality of applications than the NIH does overall. The tradition of our initial review committee has been carried over from the Division of Nursing in the Health Resources and Services Administration (HRSA), and the review committee has been under the aegis of the NIH only for about two years. This tradition involved the combining of scientific merit and funding decisions, resulting in disapproval being given for a wider range of reasons than at the NIH. The tradition is slowly changing, and the approval rate has increased from approximately 30 to 35 percent in FY 1985 to 58 percent in FY 1988.

I would like to point out that our success rate--the number of awards made in relation to all the applications received--is very close to that of NIH overall. In FY 1988, the NCNR success rate was 27 percent and the NIH success rate was 32 percent. Since our payline in 1988, 170, was nearly the same as the overall NIH payline, 174, it is clear that NCNR is comparable to the other institutes in the overall quality of its applications.

ALZHEIMER'S DISEASE AND THE BURDEN OF CARE

Question. Last year the Committee provided the Nursing Center with $1.5 million for burden of care research especially focusing on Alzheimer's Disease, and $600,000 for research training in this area. Can you tell us how you are using this money and what you expect to learn from this effort?

Answer. Funds provided for the burden-of-care research with a special focus on Alzheimer's Disease (AD) have been allocated to both ongoing research and training grants as well as to new initiatives to stimulate research interest in this area. Four research grants and 12 research training awards are currently being supported by NCNR and we anticipate several more awards to be made before the end of FY 1989.

NCNR has also issued two program announcements inviting qualified researchers to submit applications for research and research training grants which focus on the area of caregiving for patients with Alzheimer's Disease and related disorders.

The first program announcement invites applications for research projects which will investigate the nature of caregiving and how this is affected by the unique nature of Alzheimer's Disease and related disorders. From such research efforts, NCNR expects to learn about the factors that contribute to the broad range of social, behavioral, economic and health issues related to

caregiving. Changes in the course of these diseases require modifications of patterns of caregiving and creative strategies to manage the physical needs of AD victims, as well as their difficult behaviors, such as hostility toward the person providing the care.

Research will be supported which increases our knowledge of the caregiving process, and the health risks incurred by informal caregivers. Especially needed are studies of planned interventions for reducing the burden of care. This program announcement seeks small-scale innovative interventions that can make a difference in the daily life of caregivers. Particular emphasis is also placed on research on special populations in which there has been a dearth of studies: the oldest of the old, racial and ethnic minorities, those with low income or little education, and those living in rural areas.

The second announcement explicitly indicates the interest of NCNR in supporting pre- and postdoctoral fellowships for qualified nurses in relevant topic areas and recommends as training sites established research programs such as the Alzheimer's Disease Research Centers funded by the National Institute on Aging.

In a related continuing education effort through these Research Centers, we plan to fund two or three projects that focus on the nursing care of patients with Alzheimer's Disease. NCNR is especially interested in the technology transfer of new research findings in the assessment of cognitive function, management of symptoms commonly accompanying dementia and the prevention or reduction of stress on caregivers.

NATIONAL NURSING RESEARCH AGENDA

Question. I understand that you have established seven broad priority areas and that the two priorities established for FY 1990 are work on low birth weight infants and care of HIV patients. What are the five remaining priorities and how much out of your funding do you expect will be spent on the two priorities mentioned above?

Answer. In FY 1990, the NCNR plans to spend approximately $1,320,000 in the field of research on low birth weight, and at least $999,000 in research on the care of HIV-positive patients. As you mentioned, we will be emphasizing these two very important areas of nursing research in FY 1990, by publishing the reports of the Priority Expert Panels and by using program announcements to orient research in those areas toward the topics of greatest promise.

The next three priority areas under the National Nursing Research Agenda planning process should be ready for release to the community in FY 1991. They are: Longterm Care for the Elderly, Symptom Management, and Information Systems. The sixth and seventh topics are scheduled to be completed in the following year, FY 1992, and consist of the priority areas of Health Promotion and Technology Dependency Across the Lifespan.

RESEARCH CENTERS

Question. Your budget requests $1.1 million for five research centers. I understand that in FY 1989 you expect to make awards for four centers at a total cost of $1.3 million. Is your FY 1990 request for research centers inadequate even to continue the four awards you expect to make in 1989?

Answer. Our request for FY 1990 would allow continuation of the four research centers which we are awarding this year. With the requested level of program funding in FY 1990, each center would be reduced by approximately 15.4 percent.

INTRAMURAL RESEARCH PROGRAM

Question. Most of the Institutes have an intramural program. What can you tell us about the Nursing Center's efforts to date in establishing an intramural research program?

Answer. An intramural research program is being planned in collaboration with the National Institute for Allergy and Infectious Diseases (NIAID) and the Department of Nursing at the Clinical Center, and will be implemented in FY 1990. This program will provide scientists studying nursing care issues related to AIDS an opportunity to work on a team with NIAID scientists in the NIH Clinical Center setting. NCNR intramural scientists will examine how nursing practice can minimize dysfunction and suffering due to physical and psychosocial sequelae of HIV infection, including nutritional disorders, diarrhea, fatigue, mouth lesions, or dementia. This important effort is directed toward decreasing morbidity and increasing the infected individual's ability to cope with symptoms of the disease and reactions to medication, in order to improve the quality of life and help ameliorate economic and social cost.

Although the first area of focus for the NCNR's developing intramural research initiative is AIDS, NCNR hopes eventually to include other areas of nursing research concern that lend themselves to intramural collaboration with other NIH institutes, such as the special care needs of cancer patients.

RESEARCH TRAINING INITIATIVE

Question. Because nursing research is a relatively new discipline, I understand that you put a very high priority on the training, both predoctoral and postdoctoral, of people who would be qualified to become nursing researchers. I understand that the National Academy of Sciences, as a part of their 5 year projection, recommended that you fund 270 nursing researchers in FY 1990. Do you believe the Center is remaining on target with the needs to train researchers in the field of nursing research?

Answer. Research training remains a major initiative for the NCNR. The goal of the Center is to support research trainees consistent with the recommendations of the National Academy of Sciences, which outlined the need for 320 nurse researcher trainees annually. Last year, the FY 1988 target was achieved with 194 training and career awards made. In FY 1989, we anticipate making 227 awards, again meeting the stepwise goal. Our request for FY

1990 would allow support of 223 trainees in the Non-AIDS programs of the Center. The NCNR is also committed to increasing the number of minority nurses supported in research training and encouraging nurse researchers to pursue postdoctoral study.

NATIONAL NURSING RESEARCH AGENDA

Question. What is the status of the National Research Agenda for Nursing?

Answer: Together with the National Advisory Council for Nursing Research and with nursing and interdisciplinary expert scientists from around the country, the National Nursing Research Agenda (NNRA) is being developed as a formal way to establish priorities for nursing science, to identify areas of scientific opportunity, and to increase the depth of the knowledge base for nursing practice. The nursing community has applauded the NNRA and the leadership role NCNR has taken in its development.

Seven priority areas have been identified, two of which will be ready for research emphasis in FY 1990. They are Low Birthweight: Mothers and Infants, and HIV Infection: Prevention and Care. The next three priority areas will be ready for release to the nursing research community in FY 1991: Longterm Care for the Elderly, Symptom Management, and Information Systems. In FY 1992, the remaining two priority areas--Health Promotion and Technology Dependency Across the Lifespan--will be finished and may be expected to influence the field of nursing science.

ALZHEIMER'S DISEASE AND THE BURDEN OF CARE

Question. How long has the joint program announcement between NCNR and the National Institute on Aging inviting research and training proposals on strategies to assist the caregiver and patient with Alzheimer's disease been released? What has been the response?

Answer. The joint announcement between NCNR and the National Institute on Aging inviting research and training proposals on strategies to assist the caregiver and patient with Alzheimer's Disease was released on February 24, 1989. The National Institute of Mental Health and the National Center for Health Services Research are also participating in this program announcement and are supporting research in this field. Although it is too early to judge the number of applications and projects that will result from this program announcement, this initiative has been well received in the community as evidenced by the telephone response from potential applicants, who have been enthusiastic. We will be pleased to provide you with the number of applications received once we have that data.

Question. What has been the response to the second announcement in the area of research training to encourage trainees in the field of caregiver research, especially relating to Alzheimer's Disease and similar disorders?

Answer. An early positive response to the NCNR program announcement encouraging research trainees to focus their studies in the field of Alzheimer's disease and related disorders has been

noted as a result of the number of phone inquiries we have received. A number of potential applicants have sought information on the locations of the Alzheimer's Disease Research Centers funded by the National Institute on Aging. They have indicated an interest in linking with these Centers for research training, as the program announcement suggested. It is too early for us to measure the response in terms of applications received since we have not yet reached the application receipt deadline. We will be pleased to provide you with the exact number of applications received once we have that data.

COLLABORATIVE RESEARCH

Question. What have been the results of some of your collaborative research efforts with other agencies? Have any results been applied to actual cases (such as the FY 1988 project entitled "A Study on Nurse Home Visitations")?

Answer. In FY 1988, NCNR collaborated with 13 Federal agencies and NIH institutes in funding ten research projects. For example, we are supporting in conjunction with the Division of Nursing in HRSA, research and demonstration studies on innovative models of nursing care in hospitals. The expectation is that the development of nursing practice models will facilitate collaborative practice by increasing the nurses' role in clinical decision making, improving the retention of nurses, and assuring the provision of high quality care in urban and rural areas.

Together with the National Cancer Institute, we are supporting a study of preparation of patients for radiotherapy in cancer treatment. NCNR has funded collaborative projects with both the National Institute of Arthritis and Musculoskeletal and Skin Diseases and the National Library of Medicine, respectively, to undertake a basic study of atrophy in skeletal muscle and to develop a computerized taxonomy for nursing interventions. However, because each of these 5-year projects is still in the first year of funding, results are not yet available.

In collaboration with the Office of Maternal and Child Health Research, the Office of Assistant Secretary for Planning and Evaluation, and the Family Support Administration, NCNR is funding a project entitled, "A Study on Nurse Home Visitations" in Memphis, Tennessee. This study is an urban replication of a home visitation project which focused on a primarily rural, white population in Elmira, New York, in which the effectiveness of nurse home visits to socially disadvantaged, adolescent, or unwed mothers and their first born children were evaluated. The findings of the Elmira study revealed that for women who received nurse home visits both before and after delivery, there were significantly fewer case reports of child abuse or neglect. In addition, the teenage mothers expressed greater concern about their children's behavior, had a more rapid return to school or an increase in the number of months employed, and had fewer subsequent pregnancies. Also, the infants of the visited mothers were bigger at birth, maintained better nutritional status, and had fewer accidents and illnesses. The aim of the present study is to determine whether the promising results of the Elmira study can be replicated with poor black families in the urban setting of Memphis, Tennessee.

JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. PHILIP E. SCHAMBRA, DIRECTOR

SUMMARY STATEMENT

Senator HARKIN. Last, we will go to the Fogarty International Center. Dr. Schambra.

Dr. SCHAMBRA. Thank you, Mr. Chairman. In its 20-year history the Fogarty International Center has become recognized throughout the world as a leader in international health. As the international arm of NIH, the Fogarty International Center is focused on three challenges: Promoting research on diseases globally, training biomedical scientists worldwide, and developing international scientific cooperation against disease.

I would like to cite some examples of our accomplishments. Through our Scholars-In-Residence and International Studies Programs we have brought together scientists from around the world to develop new strategies utilizing genetic information to prevent cancer and coronary artery disease.

To date, our International Research Fellowship Program has trained over 2,600 foreign biomedical scientists from 55 countries. We know that more than 90 percent have returned to their homelands and many are now in high scientific, academic, and administrative positions there. Their research contributions have been many and varied. For example, a fellow from Ireland developed monoclonal antibodies to detect brain tumors.

To help the United States keep abreast of scientific breakthroughs in other countries, the FIC supports a select few American scientists to conduct research in foreign laboratories. A recent example of their work is a study of genetic factors that control the immune response, basic research that will produce new knowledge about diseases such as AIDS.

Bilateral agreements with 39 countries offer opportunities for American and foreign scientists to cooperate on a broad spectrum of scientific and health problems. For example, the presidential initiative with India in science and technology has enabled American and Indian scientists to develop programs to prevent blindness by treatment with vitamin A.

Our programs in AIDS will make an important contribution to dealing with this disease. Our international training grants in AIDS epidemiology will enable scientists from 21 countries in Latin America, Africa, and Asia to learn more about the epidemiology, diagnosis, prevention, and treatment of AIDS.

We have also established an International Network for AIDS research and training to link FIC and NIAID international AIDS pro-

grams and to facilitate coordination between these programs and the World Health Organization.

PREPARED STATEMENT

We look forward to continuing to work with Congress to promote international cooperation in the biomedical sciences for the benefit of all mankind. The fiscal year 1990 budget request for the FIC is $10,622,000 and does not include $4,910,000 for FIC's AIDS grants contained in the Office of the Assistant Secretary for Health, DHHS appropriation request. I will be pleased to answer any questions.

[The statement follows:]

STATEMENT OF DR. PHILIP E. SCHAMBRA

In its 20-year history, as the international division of the National Institutes of Health (NIH), the Fogarty International Center (FIC) has become recognized throughout the world as a leader in international health. The FIC has helped the NIH and the U.S. biomedical community give increased attention to a variety of important global health issues.

In supporting the NIH mission to acquire new biomedical knowledge that will lead to better health, the FIC has focused on three specific challenges: first, to promote research on diseases that know no national boundaries; second, to train junior and senior biomedical scientists worldwide to benefit U.S. research priorities; and third, to develop international cooperation and problem solving through bilateral and multilateral agreements. I want to give a few examples of each of these areas.

The programs of the FIC emphasize international efforts for the prevention and treatment of diseases. During the past 20 years through the Scholars-in-Residence Program, more than 160 eminent scientists from 25 countries have come to the NIH to collaborate on advanced studies in contemporary medicine and international health.

The accomplishments of these Scholars are impressive: the group includes two Nobel laureates and four winners of the Lasker award, as well as recipients of hundreds of other professional prizes and awards. Their accomplishments while at the NIH include an impressive array of publications on topics ranging from basic molecular biology to strategies for the prevention and treatment of disease. A few examples of Scholars' achievements are:

o Dr. Kare Berg, Scandinavia's leading clinical geneticist, in collaboration with NIH scientists, formulated new strategies utilizing genetic information for the prevention of cancer and atherosclerosis.

o Dr. Franklin Bunn of Harvard University, one of the world's foremost biochemists, analyzed the structure of hemoglobin (the component in red blood cells that carries oxygen) relating structural abnormalities to clinical disorders such as sickle cell anemia.

o Two renowned immunologists--one a Lasker Award-winning scientist from Columbia University--Dr. Elvin Kabat, and Dr. Michael Sela of the Weizmann Institute in Israel, conducted advanced studies on unique features of antibodies that produce resistance to infection. As a result of this type of basic research, we are better prepared to confront the AIDS virus.

By its very nature, science is an international enterprise and to keep abreast of breakthroughs, U.S. scientists must learn first-hand of progress that occurs elsewhere. During the past 20 years, the FIC has supported more than 600 U.S. scientists who conducted research in laboratories abroad. And this support continues. This year an Ohio State University medical scientist, collaborating with researchers in London, used molecular biology techniques to identify the virulence factors associated with E. coli infections that have

been causally identified with hemorrhagic colitis and human uremic syndrome. These are serious human illnesses that have resulted in high fatality rates, especially in institutional settings such as nursing homes and infants in nurseries. Another U.S. scientist, from the Medical University of South Carolina, is in Cambridge, England, studying genetic factors that control the immune response. From this type of basic research will come new knowledge about diseases such as AIDS.

Since World War II, the U.S. has attracted young men and women from the world over. After their U.S. training, they have returned home eager to embark on a career in medical research. Over the past 30 years, the FIC and its predecessor unit at the NIH have provided training in U.S. laboratories for over 2,600 scientists from 55 countries through the International Research Fellowship Program (IRF). In Finland alone, more than one-third of that country's biomedical scientists have trained and conducted research in the United States. In countries of the developing world, the IRF Program supported advanced research training of approximately 800 fellows. Many are now established scientists in their own countries, passing on their U.S. training to the next generation. The intent of this program is being fulfilled in that current fellows are both conducting international collaborative research and sharing scientific knowledge around the world. In FY 1989, we initiated the 2-year IRF award to allow fellows additional time in the United States for their research. Examples of the scientific contributions of International Research Fellows include:

o In diabetes research, the discovery of the nature of the receptor for insulin by a fellow from France;

o In cancer research, development of monoclonal antibodies to examine brain tumors by a fellow from Ireland; and

o In hepatitis research, the analysis of the genetic component of the hepatitis B virus gene by a fellow from Chile.

The FIC, on behalf of the NIH, has supported the development of mutually beneficial bilateral agreements. In 20 years we have administered more than 70 international agreements with 30 countries. These agreements have made major contributions to the resolution of a broad spectrum of scientific and health problems, and provide the structure in which full-scale collaboration and a more open exchange of scientific information can occur. For example:

o The Presidential initiative with India in science and technology has enabled U.S. and Indian scientists to develop programs to prevent blindness by treatment with Vitamin A.

o Collaboration with Italy under a science and technology agreement has provided invaluable supplementary data to U.S. studies on diabetes, gastric cancers and age-related cataracts through access to unique population groups.

o The U.S.-U.S.S.R. health agreement has resulted in a number of accomplishments, particularly in the areas of cardio-pulmonary diseases, arthritis, and eye disease. Recently two new areas of

concern to the NIH, Primatology and Human Immunodeficiency Virus Infection, were added to this agreement.

The FIC Special International AIDS Program provides important opportunities for the future. In response to the world crisis to prevent and treat AIDS, the FIC is playing a central role in promoting international scientific collaboration, the key to eventual successful control of this epidemic.

In an effort to increase the capability of scientists in foreign countries, especially developing countries, to conduct epidemiological research related to AIDS and to make international collaboration on drug and vaccine trials feasible, the FIC has developed International Training Grants in Epidemiology Related to AIDS. T[illegible] program supports five types of training including research training leading to advanced degrees, training in field studies, short-term comprehensive courses in epidemiology or laboratory procedures, and applied courses for health professionals. These researchers and health personnel will develop and improve their skills in epidemiology, diagnosis, prevention, and treatment of AIDS. These training grants support scientists from eight countries in Latin America and the Caribbean, eight countries in Africa, and five countries in Asia.

A second FIC AIDS program supports international postdoctoral research training in AIDS. Funds have been awarded to four U.S. institutions for international collaborative research and research training for the diagnosis, prevention, and treatment of AIDS. Priority is given to AIDS researchers from developing countries and researchers are being trained in both the United States and abroad.

The FIC has recently joined forces with the National Institute of Allergy and Infectious Diseases (NIAID) to establish an International Network for AIDS Research and Training. This network links FIC-sponsored AIDS programs with the NIAID-funded International Collaboration in AIDS Research Program. The purpose of the network is to facilitate coordination between the programs and the World Health Organization, identify research and training needs, and allow for improved efforts in responding to emerging problems.

Twenty-five years ago, the late Congressman John Fogarty proposed an international center at the NIH--as he phrased it--"dedicated to international cooperation in the interests of the health of mankind." The John E. Fogarty International Center for Advanced Study in the Health Sciences, named in honor of Congressman Fogarty, has accomplished much in its first two decades. But there is still much to do. We look forward to continuing to work with Congress to promote international cooperation in the biomedical sciences for the benefit of all mankind.

The FY 1990 budget request for the FIC is $10,622,000. I will be pleased to answer any questions you may have.

EFFECT OF INTERNATIONAL PROGRAMS

Senator HARKIN. Are these programs that you have—the three programs that you have, are they really necessary in the advancement of science or are these foreign policy tools that we use, or both?

Dr. SCHAMBRA. In each case, the program is necessary for and supports the advancement of research on the prevention and treatment of disease. However, I do think that to the extent long-term collaborations are built between U.S. and foreign scientists, some foreign policy goals also are served.

The fact is, that over the past 20, 30, 40 years, a number of countries abroad, particularly Japan and Western Europe, have raised their level of scientific effort to a level in many cases equal to that of the United States and in selected areas, even in advance, so it is really incumbent upon us, I think, through our international programs, to try to take advantage of that for our own interests and they certainly serve beneficial diplomatic purposes as well as we develop scientist to scientist and institution to institution cooperation.

Senator HARKIN. Last year NIH awarded $33.7 million in grants through the normal peer review process to foreign scientists and $14.1 million in contracts to foreign nationals. It seems that we have this process to enlist the brightest and best from overseas. What additional work can the Fogarty Center do?

Dr. SCHAMBRA. The FIC Program does not overlap with this effort. As a Center for Advanced Study in the Health Sciences, FIC supports eminent distinguished foreign scientists to conduct advanced research on the NIH campus, together with Fogarty international junior scientists. FIC's extramural program, in distinction from the rest of NIH, supports outstanding American scientists to conduct research abroad and to return with the latest biotechnologies from Europe and elsewhere.

Finally, through the administration of bilateral agreements, Fogarty establishes linkages between American scientists and those in foreign countries to work on important international health problems.

FULL-TIME EQUIVALENT EMPLOYMENT

Senator HARKIN. How many FTE's do you have?

Dr. SCHAMBRA. We have 59 FTE's in the present fiscal year: 58 non-AIDS and 1 AIDS.

Senator HARKIN. How does that compare to last year?

Dr. SCHAMBRA. In fiscal year 1988 we had 58 non-AIDS and no AIDS FTE's.

AIDS

Senator HARKIN. You have—in the 1990 budget you have $4.9 million for two new AIDS initiatives.

Dr. SCHAMBRA. That is basically a continuation of the programs committed in fiscal year 1988 and fiscal year 1989.

FUTURE PLANS

Senator HARKIN. As the new director, do you have any plans for changing the focus or direction of the center?

Dr. SCHAMBRA. Senator, this is certainly something I have been thinking about. It is probably evident to you that the Fogarty International Center is the smallest component of the NIH budget. I think we are about two-tenths of 1 percent of the total NIH budget. That is on the one hand.

On the other hand, we have the important responsibility of facilitating the initiation of international biomedical research conducted by all of the Institutes of the NIH. We achieve this by administering and coordinating NIH involvement in 72 bilateral agreements with 39 countries.

As I look at the Fogarty Center and at the accomplishments of NIH, I think that American scientists are doing a very good job in addressing health problems which affect Americans and citizens of developed countries around the world—Western Europe and Japan. But, I think that we can do more to help leading scientists of developed countries to pool their knowledge to deal with such chronic disease problems as cancer and heart disease.

As I look to the future, Senator, a second challenge concerns an expanded role for the Fogarty International Center to facilitate collaboration between American scientists and scientists from developing countries in Latin America, Africa, and Asia to conquer the great killer diseases which take approximately 25 million lives every year. As long as these diseases exist, they are a threat to Americans.

In summary then, within the limits of the Fogarty Center's resources, what I want to do, first, is to sharpen our focus in dealing with Europe and Japan to increase our access to their advanced technology to help solve the chronic diseases afflicting primarily western man, or populations in industrialized countries; and, second, to increase our efforts on the acute and chronic diseases which affect the people of Latin America, Africa, and Asia. These diseases, as we now know, can be a threat to Americans when they spread to this country.

Senator HARKIN. Thank you very much, and thank you all very much. Dr. Wyngaarden, thank you again for your excellent leadership from the National Institutes of Health.

Again, I think of all of the entities that have been set up by the Government in the past 50 years I would say that NIH is one that has a very high level of support, positive support by the American people—rightfully so—and I quite frankly am embarrassed by some of the sums we see in this budget proposal.

When you consider that the professional judgment budget is about $500 million more and some of these things we are making great progress in, it seems a shame that we cannot just come up with that money.

We are going to have some tough budget battles this year—very tough—and that is why I ask for your help in these procurement areas. Any place we can tighten down on, save a few here, it sure helps us out a lot and if I can then go to my colleagues and budget people and say, look, we have made these savings—we have tight-

ened down, you cannot accuse us of just not looking for places that we can tighten down and saved, we have done it in the National Institutes of Health, I think that buttresses our argument to get additional funds.

So again, I just want to close on a positive note by again commending you and all your Institute directors and all that you do for the health and welfare of not only the American people but indeed, all of humankind.

Dr. WYNGAARDEN. Mr. Chairman, let me thank you on behalf of myself and my colleagues at NIH. Thank you and the entire committee for your great interest in the budget of the National Institutes of Health and your personal interest in visiting us and we look forward to working with you in the future.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator HARKIN. Thank you. There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing, but were submitted to the Institute for response subsequent to the hearing:]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

EFFECT OF INTERNATIONAL PROGRAMS

Question. Fogarty conducts three basic programs to bring foreign scientists to the United States and to send U.S. scientists to foreign countries. These are the: Scholars-in-Residence program that will bring 10 foreign scientists to NIH in FY 1990; International Research Fellowship program that will bring 91 foreign scientists to the United States in FY 1990; and Senior International Fellowship program that will send 28 U.S. scientists overseas in FY 1990. Dr. Schambra, do you consider these programs to be necessary to the advancement of science or are they foreign policy tools?

Answer. In each case, the program is necessary for and supports the advancement of research on the prevention and treatment of diseases. Let me provide some examples:

Through the Scholars-in-Residence Program, biomedical scientists of international repute spend a year at the NIH conducting research with NIH intramural scientists on important diseases of concern to the U.S. and worldwide. Examples of research accomplishments include: recognition of the importance of genetic factors in atherosclerosis, underscored by the recognition of gene interaction in the pathogenesis of this disorder; and identification of the chemical substance on the exterior of a virus which binds to a specific site on the cell surface. Such knowledge will be important in the design of drugs for viral infections.

The Senior International Fellowship Program supports senior scientists from American universities to conduct research in leading foreign institutions, such as the Pasteur Institute in France and the Max Planck Institute in Germany. This program enhances international research collaboration, but most importantly, this program facilitates American access to advanced biomedical technology and the transfer of this technology to American universities. Examples of research conducted abroad by these Americans include: identification of the virulence factors associated with E. coli infections that have been identified with hemorrhagic colitis and human uremic syndrome; and the identification of genes that determine the structure of antibodies, a finding that will be important to other research on immune deficiency diseases.

Since World War II, the U.S. has attracted young men and women from the world over. After their U.S. training, they have returned home eager to embark on a career in medical research. Over the past 30 years, the FIC and its predecessor unit at the NIH have provided training in U.S. laboratories for over 2,600 younger scientists from 55 countries through the International Research Fellowship (IRF) Program. In Finland alone, more than one-third of that country's biomedical scientists have trained and conducted research in the United States. The program recently underwent extensive evaluation by an outside review group who came to the conclusion that this was an extremely effective program. They found that an exceptionally high rate of the young scientists who were trained under this

program returned home to become scientific leaders, to train younger scientists in their own countries, and to maintain extensive research collaboration with their American colleagues. Examples of the scientific contributions of International Research Fellows include: in diabetes research, the discovery of the nature of the receptor for insulin; in cancer research, development of monoclonal antibodies to examine brain tumors; and in hepatitis research, the analysis of the genetic component of the hepatitis B virus gene.

Question. Dr. Schambra, as you know, NIH awarded $33.7 million in grants through the normal peer review process to foreign scientists in fiscal year 1988 and $14.1 million in contracts to foreign nationals. It seems through this process we can always enlist the best and the brightest from overseas. What additional can the Fogarty programs add to this regular process?

Answer. In regard to your first comment concerning the NIH enlisting the best and the brightest senior scientists from abroad to do research in their own countries, it is certainly true that in selected areas of research the Institutes award research grants and contracts to foreign investigators when this is in the best interest of the U.S. to advance our health research priorities. Fogarty programs do not duplicate these Institute international research efforts.

What the Institute programs do not do, but Fogarty programs do, is support senior American university scientists to conduct research abroad in the very best laboratories, and in this way gain access to emerging new technologies and bring them back to this country. Three notable examples of new technologies that were developed in Europe and that revolutionized medical research include: at Cambridge, England, the discovery of hybridomas for the production of homogenous antibodies; at Karolinska, Stockholm, the discovery of the ELISA blood test for the detection of antibodies to viruses such as hepatitis B and AIDS (as a result of the use of this blood test, the blood supply is now safe and there is little danger of acquiring these diseases by blood transfusion); and at Basel, Switzerland, the discovery of the novel technique to detect the unexpected and unusual genetic processes employed in the body to produce on demand thousands of different antibodies in response to the many different infectious diseases. FIC programs are designed to support American university scientists for a period of intensive research in outstanding foreign laboratories such as these. For example, since 1979, nine medical scientists from the University of Iowa have had a Fogarty Senior International Fellowship to conduct research in England, West Germany, Switzerland and Holland.

Finally, there is no mechanism under the grants programs of the other institutes to support such senior eminent scientists as Fogarty Scholars-in-Residence on the NIH campus. In consultation with NIH intramural scientists and the FIC Advisory Board, Fogarty selects scientists for this award, many of whom are from Europe. Eight to ten such scholars are in residence at any one time. For example, Dr. Peter Perlmann of the Karolinska Institute in Stockholm, and the discoverer of the ELISA test, is currently a Scholar-in-Residence conducting research full-time with NIH scientists in the malaria laboratory in an effort to develop a vaccine against this disease. The Scholars-in Residence program is

the only mechanism available at the NIH to bring such eminent international scientists to the NIH campus. Since 1968, 171 such Scholars have been at the NIH and have been an inspiration to the young American scientists in our laboratories.

AIDS

Question. Fogarty's fiscal year 1990 budget includes $4.9 million to fund the two new AIDS initiatives that were first funded by the Congress last year. One of these efforts is focused on training grants especially for third world countries to track the progress of the disease through epidemiological research. How many years do you expect we will need to continue these grants in order to accomplish the program's purpose?

Answer. The new FIC program of International Training Grants in Epidemiology Related to AIDS represents a long-term commitment on the part of the FIC to strengthen the capacity of scientists in the United States and developing countries to conduct epidemiologic research related to AIDS and to use epidemiology in clinical trials and prevention research. The current program includes training opportunities for foreign scientists from 22 developing countries in Africa, Asia and Latin America.

These grants must be continued for at least 10 years to accomplish the program's purpose. The best estimates of the PHS and WHO are that the AIDS epidemic will continue to spread worldwide and, in particular, become serious in the developing countries and a persistent threat to the U.S. until such time as we develop a successful vaccine and a treatment which cures the infection. It is unlikely that these breakthroughs to prevent and treat this disease will come before the year 2000. Therefore, we must implement prevention programs abroad and here at home. This will require a major increase in individuals trained in epidemiology. Furthermore, testing of new vaccines and new drugs will require a cadre of epidemiologists who have the skills to conduct clinical trials. Individuals with these skills in both this country and the developing world must be trained to meet this objective. Apart from the critical importance of this epidemiology training related to AIDS, this program greatly increases the capacity of developing countries to identify the early occurrence of diseases caused by other emerging viruses. Consultants to both the FIC and other NIH institutes recently identified the need to strengthen the epidemiology capacity in developing countries so that we can stem the tide of future emerging viruses before they reach our shores.

TWO-YEAR INTERNATIONAL RESEARCH FELLOWSHIP

Question. I noticed that you are proposing to make the International Fellowship program a two-year award program in fiscal year 1990. Wouldn't it be better to offer the possibility of a one-year extension instead of making this a two-year program for everyone regardless of how well they may perform?

Answer. We feel that a two-year fellowship program is essential. In direct response to your question, the initial approval for a two-year award is contingent upon each fellow successfully completing the first year. This is determined by an

evaluation of the fellow's work by the American scientist supervisor and review by Fogarty staff. Funds are not released to support the second year if the evaluation is unsatisfactory. An important point in establishing the program as a two-year program is that most senior scientists prefer to host a scientist (U.S. citizen or foreign) for more than one year, because the first year is usually devoted to developing the laboratory methodology; the second year is when research results start to flow.

INTERNATIONAL COLLABORATIVE RESEARCH INITIATIVES

Question. Last year, this committee recommended $400,000 in additional funding (later deleted by House-Senate conferees) to take advantage of research opportunities in four additional areas of the world under the general FIC program. Please report how international collaborative research initiatives have progressed over the past year.

Answer. International collaborative research initiatives have progressed well over the past year. Although $400,000 proposed to support regional science and technology attaches, was deleted in conference, we have been able to continue past collaborative efforts and to develop some new agreements.

Specifically, in the European region, we have further developed our collaboration with institutes in France, the Federal Republic of Germany and Italy, in the areas of AIDS, musculoskeletal diseases, and cancer research. We have also initiated planning for the 1992 European Community transformations since we hope to identify ways to take full advantage of these changes.

In relation to Asia, we are developing a memorandum of understanding with a Thai insitution to undertake research training in AIDS and Cancer Therapy. We continue to work with Japan on the Human Frontiers Science Program and other collaborative agreements.

In Latin America, we are entering final negotiations with Brazil on collaborative biomedical research on infectious and cardiovascular diseases, epidemiology and the neurosciences to be pursued under the U.S.-Brazil Science and Technology Agreement. Recent discussions with Mexican officials may also lead to further collaboration on diabetes and child health and human development. Based to a significant degree on growing congressional interest, this year we have undertaken a broad effort to expand collaboration with Latin American counterparts.

Through our international training grants in AIDS epidemiology, scientists from 21 countries, including 8 countries in Africa, will learn more about the epidemiology, diagnosis, prevention and treatment of AIDS. In a region such as Africa, this program will greatly increase the capacity of these 8 countries to identify the early occurrence of diseases such as AIDS.

Overall, we continue to develop and enhance collaboration with the most creative foreign scientists in the world.

AREAS REQUIRING ADDITIONAL FUNDING

Question. Do you still feel that additional funding, particularly in AIDS related areas, is warranted this year?

Answer. Yes, definitely so. In fact, just to meet the commitments under our new program of International Training Grants in Epidemiology Related to AIDS requires at least an additional $1,500,000. As I indicated in my response to your question concerning the length of these training programs, let me emphasize again that individuals trained in epidemiology are going to be essential to these prevention programs until such time as we have a specific vaccine and drugs for treatment. And, again as I stated before, these specially trained people, of whom we have very few now not only here but especially in the developing countries, will also be needed to conduct treatment trials and vaccine trials abroad.

Question. What other international programs under FIC would you consider to require increased funding?

Answer. In addition to the $1,500,000 to meet our commitments under the FIC's training grants in AIDS, we believe the following FIC international programs require additional funding:

One million dollars is needed for new collaborative research activities, specifically focused in Latin America, on such health problems as AIDS, parasitic and neurological diseases, and malaria, and the development of new research strategies for the treatment and prevention of these diseases that threaten the lives of not only Latin Americans but the health of people worldwide.

An additional $600,000 is needed to increase International Research Fellowship awards to scientists from countries in Latin America, with expansion in several countries in eastern Europe where our programs currently are not operative.

An additional $284,000 is needed to support three additional Fogarty Scholars, with emphasis on recruitment of scientists from Latin American countries, with expertise in fields such as AIDS, the human genome, and tropical diseases.

And finally, an additional $1,000,000 is needed to support four science attaches, in Western Europe, Asia, Latin America and Africa, to facilitate biomedical research efforts between American scientists and those in foreign countries.

INTERNATIONAL NURSING RESEARCH INITIATIVE

Question. What new initiatives in international nursing research were undertaken by FIC last year, in light of the continuing nursing crisis in this country?

Answer. The FIC has expanded our efforts internationally to recruit additional nurses into research and research training. The FIC has announced the availability of FIC's fellowship, scholarship, and exchange programs to U.S. and foreign nursing research and research training institutions.

In FY 1987 and FY 1988, five awards in FIC's Senior International Fellowship Program were made to nurses. Examples of these projects include a study of collaborative decision-making in nursing (in Norway); a study of hypertension self-regulation (in Japan); a comparative study of confusion in elderly hip fracture patients (in England); and non-invasive strategies in urinary incontinence (in England). Findings from these studies will be integrated by these U.S. nurse researchers into clinical research and practice in the United States.

Nurses are also taking advantage of the postdoctoral research training in AIDS and the training offered under FIC's two AIDS programs.

The nurse anthropologist on FIC's Advisory Board will represent the FIC at the International Council of Nurses in Korea in May and at the meeting of international nurse researchers in Taiwan in June, in order to further publicize the availability of research training for nurses under FIC's programs.

In addition, the National Center for Nursing Research is currently involved within the United States in a series of projects on innovative clinical nursing practices which would be the subject of future international comparative studies.

Question. Are you satisfied that the overall FIC program is receiving the fiscal attention that it deserves and do you have any additional recommendations for the committee?

Answer. The FIC is the smallest component of the NIH with about 2/10ths of one percent of the total NIH appropriation. In addition, the Center has lost ground in terms of constant dollars over the past 10 years, while other components of the NIH have grown, from 10 to 80 percent, in constant dollars. Because the FIC budget has lost ground in constant dollars over the years, the awards to the Scholars-in-Residence working on the NIH campus and to the senior American scientists studying abroad have not been increased to keep up with inflation. For example, we have not increased the stipends to Americans conducting research abroad in the last 7 years. The situation is similar with our Scholars-in-Residence who had a very modest increase in 1987. If this lag in stipend persists, we may have difficulty attracting the very best internationally recognized scientists to the Scholars program.

In short, the Fogarty Center accomplishes its mission, in part, through salary support for individual scientists to conduct research either in the U.S. or abroad and our programs must be competitive.

GORGAS MEMORIAL INSTITUTE

Question. Last year, the committee recommended that the grant to GMI/GML should be peer reviewed and competed for every 3-5 years. Further, the committee recommended that GMI/GML work should be reviewed and awarded by the newly established Division of Tropical Medicine of NIAID to insure integrated research in tropical medicine. What are your thoughts on those recommendations and how does FIC plan to address those issues in coming years?

Answer. The committee's recommendation to transfer the Gorgas Memorial Institute to the National Institute for Allergy and Infectious Diseases (NIAID) has been implemented. I believe that this transfer will help the NIH better integrate research in tropical medicine and that the programs of the Gorgas Memorial Laboratory will complement this research effort.

The transfer of the Gorgas Memorial Laboratory funding to the NIAID officially terminates FIC's formal involvement in the funding and oversight of the Laboratory. We will, however, offer the benefit of our experience with the Gorgas Laboratory as well as our overall expertise in international research activities to assist the NIAID if they so desire. In fact, we have participated with the NIAID and Gorgas management staff to discuss the transition from FIC funding to competitive, peer-reviewed grant support. As this new support mechanism evolves, I anticipate that FIC involvement in NIAID/GMI activities will end.

Question. Has there been any more progress in obtaining funding for GMI/GML from Latin American and other tropical countries?

Answer. Attempts to obtain additional funding for GMI/GML from Latin American countries have not been successful. They continue to receive support from Panama, however.

Question. What are your overall views on the status of GMI/GML today?

Answer. The GMI/GML's status is closely tied to the political situation in Panama. Until there is greater stability within Panama, the Laboratory will have considerable difficulty in recruiting research staff and conducting normal operations. This is unfortunate since GMI/GML is the only U.S.-managed laboratory located in Latin America and could serve to enhance the Administration's efforts to improve collaboration with our neighbors in the southern hemisphere. It offers the United States the capacity to conduct long-term field studies of tropical diseases and provides the capacity to detect new or unusual outbreaks of disease that could threaten our citizens.

FIC PROGRAM OBJECTIVES

Question. Do you have any other comments about the overall FIC program or any other recommendations to the committee as to how the FIC program could be improved?

Answer. In response to your question, I should like to return briefly to the central mission of the Fogarty. Indeed, that mission is spelled out in the title: The Fogarty International Center for the Advanced Study of the Health Sciences. To achieve this objective, the efforts of Fogarty have been directed primarily to the support of people rather than research projects.

In a very real sense, the FIC has an intramural program and an extramural program, just as is the case for the other institutes. Let me explain. Each year, 8 to 10 eminent medical scientists are in residence on the NIH campus as Fogarty Scholars-in-Residence to

carry out research and advanced study on a spectrum of normal and abnormal biological processes involved in health and disease. Because of personnel ceilings at the NIH and other difficulties in recruiting senior scientists to the staff, this program is currently the major avenue, if not the only one, for the recruitment, on a temporary basis, of distinguished scientists to the campus to work alongside our junior and senior scientists in all of the categorical institutes.

Another aspect of the intramural program which has an international dimension concerns the large cadre of junior foreign fellows who work in the laboratories on the NIH campus. Fogarty is responsible for all matters pertaining to the arrangements, including obtaining concurrence between governments, for the temporary employment of these foreign scientists at the NIH. After these young men and women return to their foreign countries, many become established scientists, and achieve distinction for biomedical research. Most important, many have maintained international research collaboration with their mentor scientists here at the NIH.

The Senior International Fellowship Program is the major component of Fogarty's extramural program. Each year, 40 to 45 outstanding American scientists from universities across the country, who are in the productive mid-life of their scientific careers, receive a competitive grant to conduct research abroad in the leading laboratories of Europe and elsewhere. There are three important consequences of this program which need to be emphasized.

First, it facilitates American access to advanced biotechnology in other developed countries and the transfer of this technology to American universities.

Second, this program provides a mechanism for our leading scientists to pool their knowledge with foreign colleagues and to conduct collaborative research, without duplication, on some of the most intractable health problems that still elude us, including cancer, heart disease, arthritis, blindness and neurological diseases.

And third, as research becomes more and more expensive, international cooperation is vital to contain costs, especially in such important areas as research on the human genome and on the applications of biotechnology. To this end, FIC plays an important role through the support of international collaboration.

The other major component of our extramural program is the International Research Fellowship Program which provides training for approximately 100 junior foreign scientists each year from 55 countries. We select the best and the brightest to conduct research in laboratories at U.S. universities. As I noted earlier, a recent evaluation of the program found that a high rate of these young scientists return home to become scientific leaders, maintaining extensive research collaboration with their American colleagues and continuing to make scientific contributions to the solution of health problems worldwide.

Another aspect of the FIC extramural program pertains to its efforts to establish linkages between American scientists and scientists in foreign countries to work on important U.S. health problems and those that have worldwide significance. This linkage is achieved in several ways. Fogarty, for example, administers the bilateral research agreements between the United States and 37 different foreign countries. The purpose of these agreements is to develop the research linkages among a worldwide network of scientists. In addition, Fogarty staff together with extramural American and international scientists develop research strategies to solve significant health problems. For example, FIC participated in convening a group of scientists headed by Dr. Joshua Lederberg, Nobel Laureate, to consider the implication of the possible emergence in the future of new, unexpected and potentially serious virus diseases such as AIDS. The purpose of this consultation was to provide the Public Health Service with advice on possible strategies to meet such a threat before its widespread occurence.

In my answers to the questions from this committee, I have outlined the needs of Fogarty to fully implement the intramural and the extramural aspects of its international research program. It is my intention for Fogarty to become, in word and in deed, an international center for the advanced study of the health sciences, which is second to none.

SUBCOMMITTEE RECESS

Senator HARKIN. The subcommittee will stand in recess until 9 a.m., Wednesday, May 3, when we will meet in SD–192 to begin our public witness hearings on the budget request.

[Whereupon, at 4:15 p.m., Monday, May 1, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, May 3.]

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